

## **Committee 14**

# **Surgery for Urinary Incontinence in Women**

### **Chair**

*A.R.B. SMITH (U.K)*

### **Members**

*R. DMOCHOWSKI (USA),*

*P. HILTON (U.K),*

*E. ROVNER (USA),*

*C.G. NILSSON (Fin)*

### **Consultants**

*F.M. REID (U.K),*

*D. CHANG (USA)*

## CONTENTS

---

---

**INTRODUCTION**

**I. SURGERY FOR STRESS  
INCONTINENCE**

**II. CONFOUNDING VARIABLES**

**III. STRESS INCONTINENCE WITH  
PROLAPSE**

**IV. COMPLICATIONS OF SURGERY  
FOR STRESS INCONTINENCE**

**V. SURGERY FOR DETRUSOR  
OVERACTIVITY**

**VI. COMPLICATIONS OF SURGERY  
FOR DETRUSOR OVERACTIVITY**

**VII. NEUROMODULATION**

**VIII. URETHRAL DIVERTICULUM**

**IX. NON-OBSTETRIC URINARY  
FISTULAE**

**X. OUTCOME MEASURES**

**IX. ARTIFICIAL URINARY SPHINCTER  
IN WOMEN**

**REFERENCES**

# Surgery for Urinary Incontinence in Women

A.R.B. SMITH

R. DMOCHOWSKI, P. HILTON, E. ROVNER, C.G. NILSSON,  
F.M. REID, D. CHANG

## INTRODUCTION

Surgeons have been criticised for the lack of rigour with which they have analysed their results. This chapter highlights the progress made, particularly in surgery for stress incontinence where more randomised controlled trials have been reported, and illustrates areas where more studies are needed. The section on outcome measures illustrates that whilst the measurement of subjective and objective outcome may clarify the value of an operation some standardisation of outcome measures is required in order to meaningfully compare different procedures.

## I. SURGERY FOR STRESS INCONTINENCE

### 1. PROCEDURES EXCLUDING MID-URETHRAL TAPES

The practice of surgical treatment for stress urinary incontinence has changed dramatically over the last decade; the number of procedures undertaken appears to be increasing, and the shift in relative numbers of different procedures has been remarkable. In England between 1997-'98 and 2005-'06 the annual number of operations undertaken for stress urinary incontinence (SUI) increased by 28%, despite over 90% reduction in the numbers of colposuspension and needle suspension procedures, and 50% reduction in bladder neck buttress, sling and urethral bulking procedures. The increase was entirely due to the rapid dissemination of the Tension-free Vaginal Tape (Gynecare®, Ethicon, Somerville, NJ) in 1998, and similar minimally invasive synthetic sub urethral sling procedures subsequently (Hilton, 2008) [1]

Whilst these trends may be in line with currently available evidence, other changes in practice seem to be proceeding in advance of high quality evidence; the drivers behind such changes in practice have recently been reviewed (Hilton, 2008)[1].

In their systematic review published in 1996, Black and Downs drew attention to the deficiencies of the

literature available at the time (Black & Downs, 1996, Downs & Black, 1996) [2,3]. In particular they highlighted the difficulties posed by case definition and the uniformity of surgical technique both between and within surgical teams, the problem of variations in outcome measures used, the handling of confounding variables, the generalisability or external validity of the results, and the lack of statistical power in most studies. Most systematic reviews published since on the topic of surgery for incontinence in general or relating to individual surgical procedures have made similar comments regarding the quality of available evidence. Hence recommendations must be made not only on the amount of evidence available, but on the quality of that evidence. Several systems for grading the quality of studies have been proposed, including that initially presented by Black and Downs (Black & Downs, 1996, Downs & Black, 1996) [2,3], and that proposed by the GRADE group (Grading of Recommendations Assessment, Development and Evaluation) in their publications (Atkins *et al.*, 2004a, Atkins *et al.*, 2004b, Atkins *et al.*, 2005) [4,5,6] and on their website, <http://www.gradeworkinggroup.org>. A recent series of articles in the BMJ explain the GRADE system in more detail (Guyatt *et al.*, 2008a, Guyatt *et al.*, 2008b, Guyatt *et al.*, 2008c) [7,8,9].

The duration of follow-up is another factor affecting the validity of comparison between studies of efficacy and safety. In the first edition of this consultation, it was suggested that short term surgical follow-up should be considered as being up to 3 months, medium term from 3 to 12 months, and long term over 12 months (Mattiasson *et al.*, 1999) [10]. There are occasions when case reports or short-term trial follow up and the early presentation of outcomes may be not only appropriate but also indeed mandatory. If serious unexpected adverse events come to light during early experience with procedures, colleagues and patients must be made aware. Where significant differences in efficacy or safety outcomes become apparent before the end of a study, it may be ethically unacceptable to continue randomisation. It is unlikely however that these factors are at play in the majority of studies of less than a year follow-up. In a recent review on long-term studies of pelvic floor dysfunction Hilton found that of 127 papers published in the last 25 years on

incontinence or pelvic organ prolapse (POP) which included the phrase 'long term' in their title or abstract, follow-up periods ranged from 1 to 14 years, with a mean of 59.5 months in those investigating surgical treatments (Hilton, 2008) [1]. Whilst highlighting some of the difficulties inherent both in undertaking and interpreting long-term studies, he argued for more long-term studies of high quality, and for a change in definition of 'long-term' to imply outcome at 5 years or more (Hilton, 2008) [1].

### **a) Search strategy**

This section is based on electronic searches of Medline, EMBASE, CINHALL, the Cochrane database of systematic reviews, and the NICE website ([www.nice.org.uk](http://www.nice.org.uk)) references included in identified reviews were evaluated separately. Hand searching of recent (Jan-Apr 2008) issues of American, European and British journals in urology, gynaecology and urogynaecology was undertaken, to capture recent publications not yet included in the online databases. ICS, IUGA, AUA and AUGS conference proceedings for 2007 were also reviewed. It was assumed that trials presented earlier than this would be in press if they were of sufficient quality and maturity to justify inclusion; hence older abstracts have not been considered here. A total of 5331 references were identified; excluding duplicates, there were 3650 unique references. Of these 762 were of relevance to this review of non-tape procedures. Search terms used included the following:

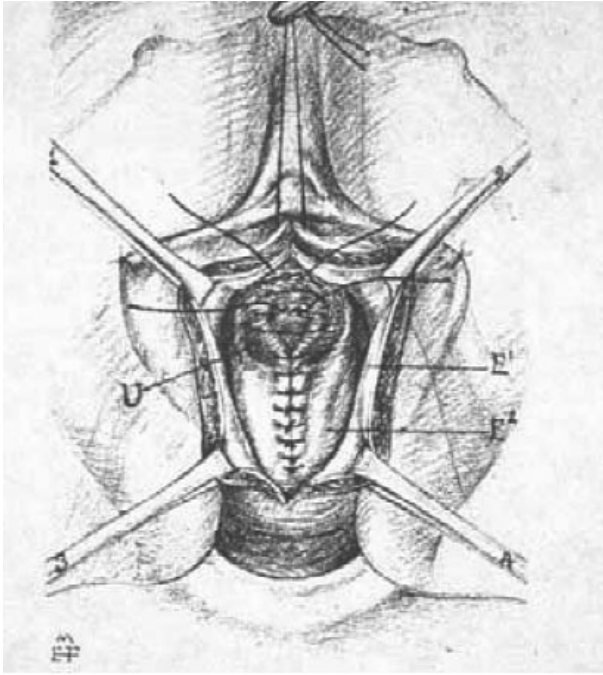
URINARY INCONTINENCE; URINARY INCONTINENCE, STRESS/; ((stress\$ or mix\$ or urg\$ or urine\$) adj3 incontinen\$); SURGICAL PROCEDURES, OPERATIVE/; SURGICAL PROCEDURES, MINIMALLY INVASIVE/; UROGENITAL SURGICAL PROCEDURES/; GYNECOLOGIC SURGICAL PROCEDURES/; UROLOGIC SURGICAL PROCEDURES/; UROGENITAL SYSTEM/su [Surgery]; URINARY TRACT/su [Surgery]; URETHRA/su [Surgery]; VAGINA/su [Surgery]; BLADDER/su [Surgery]; LIGAMENTS/su [Surgery]; ((urethra\$ or vagina\$ or bladder\$) adj3 surger\$); (colposuspension\$ or colpo suspension\$); vesicosuspension\$; urethro suspension\$; ((vesicourethra\$ or urethrovesica\$) adj3 suspens\$); colpourethrosuspension\$; (corner\$ adj3 suspension\$); (urethropex\$ or urethrocystopex\$ or cystourethropex\$ or urethro cervicopex\$); (bladder\$ adj3 buttress\$); colpofixation\$; burch\$; (marshall\$ or marchetti\$ or krantz\$ or mmk\$); ((paravagina\$ or pubococcygeal\$) adj3 repair\$); (obturator\$ adj3 (shelf\$ or shelv\$)); ((bladder\$ or neck\$ or needle\$) adj3 suspen\$); ligament fixation\$; ((pereyra\$ or stamey\$ or raz\$ or gittes\$) adj3 (suspen\$ or procedure\$)); colporrhaphy\$; ((anterior\$ or vagina\$) adj3 repair\$); (pacey\$ or kelly\$ or kennedy\$); SURGICAL MESH/; (sling\$ adj3 (procedure\$ or operat\$)); . ((bladder\$ or surgical\$ or synthetic\$ or biological\$ or autologous\$) adj3 (sling\$ or tape\$ or mesh\$)); ((urethra\$ or suburethra\$ or midurethra\$ or mid urethra\$ or

transurethra\$ or trans urethra\$ or pubovesical\$ or pubo vesical\$ or retropubic\$ or retro pubic\$ or suprapubic\$ or supra pubic\$ or pubovagina\$ or pubovagina\$ or transvagina\$ or intravagina\$ or lyodura\$) adj3 (sling\$ or mesh\$ or implant\$)); bologna\$; ingelman sundberg\$; "PROSTHESES AND IMPLANTS"/; INJECTIONS/; ((urethra\$ or suburethra\$ or midurethra\$ or mid urethra\$ or transurethra\$ or trans urethra\$ or periurethra\$ or peri urethra\$ or endourethra\$ or endo urethra\$) adj3 (inject\$ or agent\$ or bulk\$)); injectable\$; (injection\$ adj3 therap\$); (bulk\$ adj3 agent\$); contigen; COLLAGEN/; macroplastique\$; exp SILICONES/; microparticulate\$; HYALURONIC ACID/; hyaluronan therap\$; act balloon\$; CARBON/; carbon particle\$; POLYTETRAFLUORETHYLENE/; BIOCOMPATIBLE MATERIALS; URINARY SPHINCTER, ARTIFICIAL/; ((artificial\$ or prosthesis\$) adj3 (urinary or genitourinary or urethra\$ or bladder\$) adj3 sphincter\$); limit to humans; limit to female.

Relatively little high-level evidence has been published on the basis of new research since the last consultation; where available, level 1 and 2 evidence has been included in this update. Systematic reviews had already been published by the Cochrane Collaboration (Moehrer *et al.*, 2000, Bezerra *et al.*, 2001, Glazener & Cooper, 2001, Pickard *et al.*, 2003, Glazener & Cooper, 2004) [11-15], and others have been developed or updated since (Bezerra *et al.*, 2005, Lapitan *et al.*, 2005, Dean *et al.*, 2006a, Keegan *et al.*, 2007) [16-19]. The National Institute for Health and Clinical Excellence (NICE) in England has published a clinical guideline on all aspects of urinary incontinence in women, including sections on surgical treatment (National Institute for Health & Clinical Excellence, 2006b), based on systematic reviews undertaken by the National Collaborating Centre for Women's and Children's Health (National Collaborating Centre for Women's & Children's Health, 2006). NICE has also published guidance on a number of individual procedures through its Interventional Procedures Programme (National Institute for Health & Clinical Excellence, 2003, 2005a, b, 2006a). <http://www.nice.org.uk>

### **b) Anterior colporrhaphy.**

The term 'anterior colporrhaphy' tends to be used generically to describe procedures for both anterior vaginal wall prolapse and for SUI. When used to treat SUI, in addition to the reconstruction of the pubocervical fascia, it is conventional to use some form of plicating sutures to support and/or elevate the urethra and/or bladder neck. Many variations have been described often lending eponymous titles to the procedures e.g. Kelly, Kennedy, Pacey. The heterogeneity of procedures adds to the difficulties of evaluation of anterior colporrhaphy or vaginal repair procedures as a group. The place of anterior colporrhaphy in management of POP is covered elsewhere.



**Figure 1: Anterior repair illustrating sutures plicating pubocervical fascia in the midline.**

Case series indicate a wide range of continence rates following anterior colporrhaphy, ranging between 31% and 100% (Jarvis, 1994) [20] [EL=3]. Accepting variation in the procedures undertaken, the duration of follow-up considered, and the outcomes reported, cohort studies that include anterior colporrhaphy consistently show it to be associated with lower cure rates than the comparators (usually colposuspension or Marshall-Marchetti-Krantz procedure (MMK)); cure rates reported from cohort studies are 21% to 70% (National Collaborating Centre for Women's & Children's Health, 2006) [EL=3].

Several reviews of greater or lesser degrees of rigour have included anterior colporrhaphy; these include the previous editions of this chapter (Jarvis *et al.*, 1999, Smith *et al.*, 2002, Smith *et al.*, 2005)<sup>21-23</sup> and those of Jarvis (Jarvis, 1994) [20], Black (Black & Downs, 1996, Downs & Black, 1996) [2,3], the American Urological Association (Leach *et al.*, 1997) [24], Cochrane (Glazener & Cooper, 2001) [13], and NICE (National Collaborating Centre for Women's & Children's Health, 2006, National Institute for Health & Clinical Excellence, 2006b).

Many randomised trials are presented (with published abstracts) or published (as full peer-reviewed papers) on several occasions, usually with increasing duration of follow-up. The 10 trials reported in the Cochrane review of anterior vaginal repair appear as 27 abstracts or papers (Glazener & Cooper, 2001) [13]. Two of these trials, despite being undertaken over 20 years ago, have not yet appeared as full papers (Quadri *et*

*al.*, 1985, Stanton *et al.*, 1985b) [25,26]; the latter are therefore not included in the more recent NICE report.

Ten randomised trials are considered here (**Table 1**), comparing anterior colporrhaphy with pelvic floor muscle training (Klarskov *et al.*, 1986) [27], colposuspension (Bergman *et al.*, 1989a, Bergman *et al.*, 1989b, Bergman & Elia, 1995, Berglund & Lalos, 1996, Liapis *et al.*, 1996a, Liapis *et al.*, 1996b, Berglund *et al.*, 1997, Kammerer-Doak *et al.*, 1999, Klutke *et al.*, 1999, Colombo *et al.*, 2000, Lalos *et al.*, 2000) [28,30], needle suspension, (Bergman *et al.*, 1989a, Bergman *et al.*, 1989b, Bergman & Elia, 1995, Klutke *et al.*, 1999, Di Palumbo, 2003) [28-30,37,39], MMK (Liapis *et al.*, 1996b) or TVT (Meschia *et al.*, 2004) [40] (some studies having 3 intervention arms).

Excluding cases that may have appeared in more than one report, 967 women were included in these studies, 346 undergoing anterior colporrhaphy. Cure rates of 31% to 88% are reported, with anterior colporrhaphy consistently showing what are both statistically and clinically poorer outcomes than surgical comparators [EL=1].

Few trials provide follow-up beyond 12 months, although mean follow-up is provided at periods between 1 and 14 years in different studies. Where serial outcome is provided the results indicate lack of longevity. Subjective outcomes fell from 80% at 1 year to 60% at 5-7 years in one study (Berglund & Lalos, 1996, Lalos *et al.*, 2000) [31,38] [EL=2], and combined subjective and objective cures fell from 80% at 3 months to 63% at 1 year and 37% at 5 years in another (Bergman *et al.*, 1989a, Bergman & Elia, 1995) [28,30] [EL=2].

The view of the first edition of this consultation was that the major indication for bladder buttress in contemporary practice must be the patient who prefers to sacrifice some chance of becoming continent for a reduced risk of complications (Jarvis *et al.*, 1999) [21]. Subsequent editions found no new literature to justify a change to that view (Smith *et al.*, 2002, Smith *et al.*, 2005) [22,23].

The previously expressed view of the American Urological Association was that anterior repairs are the least likely of the four major operative categories (anterior repair, suburethral sling, colposuspension, long needle suspension) to be efficacious in the long-term (Leach *et al.*, 1997) [240]. The Cochrane review of anterior vaginal repair, whilst finding insufficient data to allow comparison with physical therapies, needle suspension, suburethral slings or laparoscopic retropubic suspensions, felt that there was evidence to indicate that anterior vaginal repair was less effective than open abdominal retropubic suspension in the treatment of primary urodynamic stress incontinence (SUI). The beneficial effect of the abdominal approach



**Table 1. Published level 1 & 2 evidence relating to anterior colporrhaphy for the treatment of stress urinary incontinence Notes: patient numbers are given as –no. followed up or analysed /total no. recruited /total no. in index group: analysed no. in comparator group) SS = sample size; ITT = intention to treat**

Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj)/ effect size	EL	Comments
1 (Klarskov <i>et al.</i> , 1986) [27]	RCT	PFMT	16/50 (7:9)	1y	43% vs. 78% (S – cured or improved)	2	AC or colpo depending on defect identified; only AC incl. here
2 (Bergman <i>et al.</i> , 1989a) [28]	RCT	Colposuspension	107/127 (35:38:34)	1y	63% vs. 89% vs. 65% (o) p<0.05 colposuspension vs. others	2	Data only reported for completers.
		Needle suspension					
(Bergman & Elia, 1995) [30]	RCT	Colposuspension	64/78 cured at 1y above	5y	37% vs. 82% vs. 43% (o) p<0.05 colposuspension vs. others	2	Data only on those cured at 1y.
		Needle suspension					
3 (Bergman <i>et al.</i> , 1989b) [29] (Klutke <i>et al.</i> , 1999) [36]	RCT	Colposuspension	298/339 (99:101:98)	1y	69% vs. 87% vs. 70% (o) p<0.02 colposuspension vs. others	2	All vag. hysterectomy & repair. Number randomised unclear; 339 'eligible', and 41 lost to follow-up.
		Needle suspension					
4 (Berglund & Lalos, 1996) [31] (Berglund <i>et al.</i> , 1997) [34] (Lalos <i>et al.</i> , 2000) [38]	RCT	Colposuspension	45 (15:30)	1y	47% vs. 67% (o)	2	Those with poor PF contraction excluded from repair group; no detail of randomisation given.
		Needle suspension					
5 (Liapis <i>et al.</i> , 1996a) [32]	RCT	Colposuspension	81	3y	57% vs. 88% (o); p<0.001	2	These 2 papers appear to cover the same study; one describes 2 arms at 3 years, the other 3 arms at 5 years.
		MMK					
6 (Liapis <i>et al.</i> , 1996b) [33]	RCT	Colposuspension	161/170 (50:54:51)	5y	56% vs. 89 vs. 67% (o) p<0.001 colposuspension vs. others	2	
		MMK					
7 (Kammerer-Doak <i>et al.</i> , 1999) [36]	RCT	Colposuspension	35/35 (16:19)	1y	31% vs. 89% (o) RR 0.15 (95% CI 0.04 to 0.59)	2	Anterior colporrhaphy in 100% vs. 16%; paravaginal repair in 6% vs. 42%.
		MMK					
8 (Colombo <i>et al.</i> , 2000) [37]	RCT	Colposuspension	68/71 (33:35)	≥8y	42% vs. 74% (o) OR 3.9 (95% CI 1.3 to 12.5), p=0.02	2	Vag. or abdo. hysterectomy also done; post repair in 100% vs. 34%
		MMK					
9 (Di Palumbo, 2003) [39]	RCT	Needle suspension	80/80 (52:28)	9m-4.5y	73% vs. 86% (o); p<0.01	2	2:1 randomisation; wide range of FU
		MMK					
10 (Meschia <i>et al.</i> , 2004) [40]	RCT	TVT	50/50 (25:25)	2y	56% vs. 92% (o); p<0.01	2	Recruited patients with 'occult' SUI

appeared to be longer lasting, whether or not the women had associated prolapse, and there appeared to be a greater need for repeat surgery for incontinence after vaginal repair. Although there was a higher incidence of prolapse after abdominal operations, this did not require surgical correction more often. Since postoperative surgical morbidity, quality of life measures, and economic outcomes were poorly reported, the alternative treatments could not be compared in other ways. They concluded that the use of anterior vaginal repair in the treatment of urinary incontinence should be restricted to women deemed unsuitable for alternative treatments (Glazener & Cooper, 2001) [13] [EL=1]. Given the recent developments in less invasive surgical approaches to SUI, it seems unlikely that one could identify a group of women who are suitable for anterior colporrhaphy yet who would be deemed unsuitable for some more effective alternative. Although we were not able to identify studies directly comparing of anterior colporrhaphy with mid-urethral tape procedures in the treatment of overt stress urinary incontinence, one randomised trial compared anterior colporrhaphy (including endopelvic fascial plication) with tension-free vaginal tape (TVT) in 50 women with  $\geq$ stage II anterior wall prolapse and 'occult SUI' (Meschia *et al.*, 2004) [40]. They found both subjective (96% vs. 64%;  $p=0.01$ ) and objective (92% vs. 56%;  $p<0.01$ ) continence rates to be significantly higher following insertion of TVT, with no increase in post-operative voiding problems or irritative symptoms [EL=2]. The recent NICE guidance makes a high level recommendation that anterior colporrhaphy should not be used for the treatment SUI (National Collaborating Centre for Women's & Children's Health, 2006, National Institute for Health & Clinical Excellence, 2006b) [EL=1].

We found no new high quality evidence published on anterior colporrhaphy since this latter review; indeed we found no new evidence of any level that considered the place of anterior colporrhaphy in the treatment of SUI incontinence in the absence of POP.

### Summary

Anterior colporrhaphy is comparable in effectiveness to needle suspension, and less effective than open colposuspension in the treatment of SUI; its effectiveness deteriorates substantially with time [EL=2]. Although the evidence is less robust, it appears to be less effective than the minimally invasive mid-urethral tape procedure (TVT) in the management of 'occult' SUI [EL=2].

### Recommendation

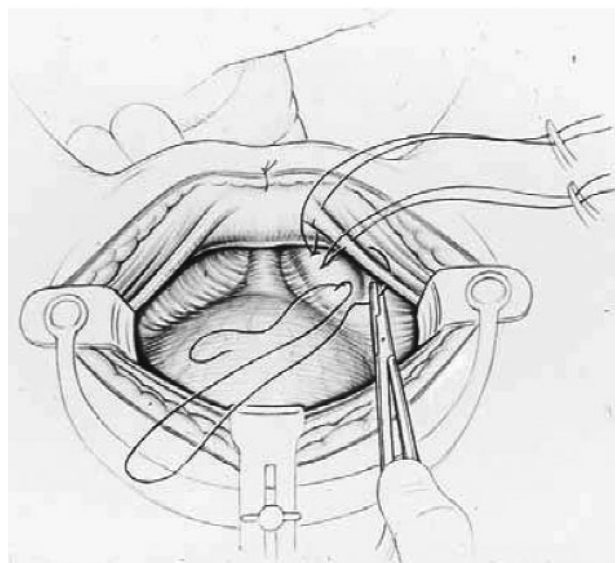
**Anterior colporrhaphy should not be used in the management of SUI alone. [Grade A]**

### c) Open colposuspension (Figure 2)

The general reviews of incontinence surgery cited

earlier all included open colposuspension of the Burch type (Burch, 1961, Burch, 1968) [41,42] amongst their considerations (Jarvis, 1994, Black & Downs, 1996, Downs & Black, 1996, Leach *et al.*, 1997, Jarvis *et al.*, 1999, Smith *et al.*, 2002, Smith *et al.*, 2005, National Collaborating Centre for Women's & Children's Health, 2006)[20,2,3, 24,21-23]; the Cochrane database includes a specific review of the procedure (Lapitan *et al.*, 2005) [17]. The latter includes details of 39 trials 12 of which were available only as abstracts, although otherwise there was virtually complete overlap with the systematic reviews from which the NICE guidance was formulated (National Collaborating Centre for Women's & Children's Health, 2006). One of those studies previously only available in abstract form has recently been published (Carey *et al.*, 2006) [43], and two others have further publications with health economic considerations or longer term follow-up (Dumville *et al.*, 2006, Ward *et al.*, 2008)[44,45].

There have been only two newly published randomised trials including colposuspension since previous systematic reviews (Albo *et al.*, 2007, Sivaslioglu *et al.*, 2007)[46,47]. In total we examined 33 published randomised trials, seven trials comparing open colposuspension with the anterior colporrhaphy, (Bergman *et al.*, 1989a, Bergman *et al.*, 1989b, Bergman & Elia, 1995, Berglund & Lalos, 1996, Liapis *et al.*, 1996a, Liapis *et al.*, 1996b, Berglund *et al.*, 1997, Kammerer-Doak *et al.*, 1999, Klutke *et al.*, 1999, Colombo *et al.*, 2000, Lalos *et al.*, 2000)[28,38], four with the MMK procedure (Colombo *et al.*, 1994, Liapis *et al.*, 1996b, Quadri *et al.*, 1999, McCrery & Thompson, 2005) [48,33,49,50], six with needle suspension (two of which also had an anterior colporrhaphy arm) (Mundy, 1983, Bergman *et al.*, 1989a, Bergman *et al.*, 1989b, German *et al.*, 1994,



**Figure 2 : Open colposuspension illustrating sutures elevating para-urethral fascia towards Cooper's ligament**

Bergman & Elia, 1995, Athanassopoulos & Barbalias, 1996, Gilja *et al.*, 1998, Klutke *et al.*, 1999) [51,28, 29,52,30,53,54,36], one with abdominal paravaginal repair (Colombo *et al.*, 1996) [55], five with traditional sling procedures (Enzelsberger *et al.*, 1996, Sand *et al.*, 2000, Demirci & Yucel, 2001, Culligan *et al.*, 2003, Bai *et al.*, 2005, Tennstedt & Urinary Incontinence Treatment Network, 2005, Albo *et al.*, 2007, Mallett *et al.*, 2008, Richter *et al.*, 2008) [56-61,46,62,63], five trials with TVT (Liapis *et al.*, 2002, Ward *et al.*, 2002, Wang & Chen, 2003, Ward *et al.*, 2004, Bai *et al.*, 2005, El-Barky *et al.*, 2005, Ward *et al.*, 2008) [64-67,46,60,68,45], one with a transobturator tape procedure (Sivaslioglu *et al.*, 2007) [47], and seven with laparoscopic colposuspension (Su *et al.*, 1997, Fathy *et al.*, 2001, Cheon *et al.*, 2003, Ankardal *et al.*, 2005, Ustun *et al.*, 2005, Carey *et al.*, 2006, Kitchener *et al.*, 2006) [69-73,43,74]. These various studies included 4161 women of whom 1900 were randomised to colposuspension; individual studies randomised between 30 and 655 women (median 90 women) (see Table 2). Objective cure rates varied between 59% and 100% (median 80%) and subjective cure rates between 71% and 100% (median 88%) [EL=1]. In common with previous systematic review supported by meta-analysis (Lapitan *et al.*, 2005) [17], the combined results from these various studies show open colposuspension to have comparable subjective and objective outcomes to both traditional sling procedures and to the newer minimally invasive mid-urethral retropubic sling procedures; it has better outcomes than anterior colporrhaphy, bladder neck needle suspension, MMK procedure and paravaginal defect repair [EL=1].

The systematic review underlying the NICE guidance on urinary incontinence reviewed cohort studies and case series for long-term follow-up data because of the relatively short duration of RCTs (National Collaborating Centre for Women's & Children's Health, 2006). They identified 3 cohort studies and 13 case series including long-term outcomes from colposuspension. The duration of follow-up of these studies ranged from a minimum of 1 year to a maximum of 18 years; most had follow-up of 5–10 years. We identified one further case control series (Dietz & Wilson, 2005) [75], one cohort study (McCracken *et al.*, 2007) [76], and three case series (Sun *et al.*, 2006, Ng *et al.*, 2007, Rardin *et al.*, 2007) [77-79] published more recently. Patient numbers in individual series ranged from 50 to 544, with a total of 3195; however, in common with most long-term surgical studies, losses to follow-up were common, and ranged up to 76% (median 40%). None of the studies considered the impact of confounding variables on the statistical significance of continence outcomes. Hence, outcome data derived from these studies must be viewed with caution; largely subjective outcomes were reported, giving between 44% and 94% cures (median 74%) [EL=3]. Case series reporting the outcome of

colposuspension for the treatment of recurrent SUI after previous surgical treatment have shown variable results, with an objective cure rate at median follow-up of 9 months of 81% and 86% in two studies (Maher *et al.*, 1999, Bidmead *et al.*, 2001) [80,81], but 61% and 65% at 5-15 years in two studies using a Kaplan-Meier analysis (Alcalay *et al.*, 1995, Thakar *et al.*, 2002) [82,83] [EL=3].

A small number of RCTs are now published giving minimum follow-up of 5 years or more; these too suffer the difficulty of high dropout rates, although 'completers' analysis indicates cure rates between 43% and 90% (median 82%) (Bergman & Elia, 1995, Liapis *et al.*, 1996b, Colombo *et al.*, 2000, Lalos *et al.*, 2000, Ward *et al.*, 2008) [30,33,37,38,45] [EL=1/2].

### Summary:

Open colposuspension has been shown to be an effective surgical treatment for stress incontinence.

In common with other procedures there is some loss of efficacy with time.

### Recommendations:

**Open retropubic colposuspension can be recommended as an effective treatment for primary stress urinary incontinence, which has longevity. [Grade A]**

**Although open colposuspension has to a large extent been superseded by the less invasive mid-urethral tapes, it should still be considered for those women in whom an open abdominal procedure is required concurrently with surgery for SUI. [Grade D]**

### d) Marshall-Marchetti-Krantz (MMK) procedure

Only level 3 evidence relating to the MMK procedure was considered in the last edition of this consultation (Smith *et al.*, 2005) [23]. Fifty eight papers, predominantly retrospective case series, published between 1951 and 1998 were reviewed, including 3238 patients. Cure rates were largely subjectively defined and averaged 88%. In many studies it was not possible to say whether procedures were carried out for primary or recurrent SUI; those that did specify gave success in 92% in primary procedures and 84% in recurrent cases (Smith *et al.*, 2005) [23].

The MMK procedure itself has not been subject to formal Cochrane review, although two studies were identified where MMK was considered as a comparator in the review of open colposuspension (Colombo *et al.*, 1994, Liapis *et al.*, 1996a) [48,32], and one where the index procedure was of the MMK type rather than Burch type (Henriksson & Ulmsten, 1978) [84], (Lapitan *et al.*, 2005) [17]. The systematic review underlying the NICE guidance on urinary incontinence (National



**Table 2. Published level 1 & 2 evidence relating to open colposuspension for the treatment of stress urinary incontinence Notes: patient numbers are given as – total no. followed up or analysed /total no. recruited (no. in index group: no. in comparator group)  
SS = sample size; ITT = intention to treat**

Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj)/ effect size	EL	Comments
1 (Mundy, 1983) <sup>51</sup>	Quasi-RCT	Needle suspension	51/51(26:25)	Min 1y	Success 88% vs 76% (s)	2	Quasi-RCT - by alternation. No ss calculation; analysis not clear if ITT.
2 (Bergman et al., 1989a) <sup>28</sup>	RCT	Ant. colporrhaphy	107/127 (38:35:34)	1y	89% vs. 63% vs. 65% (o) p<0.05 colposuspension vs. others	2	Data only reported for completers. No ss calculation
(Bergman & Eila, 1995) <sup>30</sup>		Needle suspension					
3 (Bergman et al., 1989b) <sup>29</sup> (Klutke et al., 1999) <sup>36</sup>	RCT	Ant. colporrhaphy	64/78 cured at 1y above	5y	82% vs. 37% vs. 43% (o) p<0.05 colposuspension vs. others	2	Data only on those cured at 1y. No ss calculation
		Needle suspension					
4 (Colombo et al., 1994) <sup>38</sup>	RCT	Ant. colporrhaphy	298/339 (101:99:98)	1y	87% vs. 69% vs.70% (o) p<0.02 colposuspension vs. others	2	All vag. hysterectomy & repair. Number randomised unclear; 339 'eligible', and 41 lost to follow-up.
		Needle suspension					
5 (German et al., 1994) <sup>32</sup>	RCT	MMK	80/80 (40:40)	2-7y	80% vs. 65%; p=ns (o)	2	Wide range of FU times (differed between groups). No ss calculation
6 (Berglund & Lalos, 1996) <sup>31</sup> (Berglund et al., 1997) <sup>34</sup> (Lalos et al., 2000) <sup>35</sup>	RCT	Needle suspension	50/50 (24:26)	12-44m	71% vs. 58%; 86% vs. 53% for 29 primary procedures; p<0.05	2	Randomisation not stated; analysis not clear if ITT; range of FU mean 2y.
		Pubococcygeal repair					
7 (Liapis et al., 1996a) <sup>32</sup> (Liapis et al., 1996b) <sup>33</sup>	RCT	Ant. colporrhaphy	45 (30:15)	1y	67% vs. 47% (o)	2	Those with poor PF contraction excluded from repair group; no detail of randomisation given.
		MMK					
8 (Athanasopoulos & Barbali, 1996) <sup>53</sup>	RCT	Ant. colporrhaphy	81	3y	88% vs.57%; p<0.001 (o)	2	These 2 papers appear to cover the same study; one describes 2 arms at 3 years, the other 3 arms at 5 years.
		MMK					
9	Quasi-RCT	Needle suspension	51/51 (27:24)	8-27m	74% vs. 71%; p=ns (o)	2	Quasi-RCT – randomised by DoB. No ss calculation; analysis not clear if ITT.

**Table 2. Published level 1 & 2 evidence relating to open colposuspension for the treatment of stress urinary incontinence (Continued) Notes: patient numbers are given as – total no. followed up or analysed /total no. recruited (no. in index group: no. in comparator group) SS = sample size; ITT = intention to treat**

Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj) effect size	EL	Comments
10 (Colombo <i>et al.</i> , 1996) [55]	RCT	Paravaginal repair	36/36 (18:18)	2y	100% vs. 61%; p=0.004 (o)	2	No ss calculation, but discontinued recruitment early for ethical reasons.
11 (Enzelsberger <i>et al.</i> , 1996) [56]	RCT	Slings (dura mater)	72/72 (36:36)	32-48m	86% vs. 92%	2	No ss calculation; analysis not clear if ITT.
12 (Su <i>et al.</i> , 1997) [69]	RCT	Lap colpo	92/92 (46:46)	6m	96% vs. 80%; p=0.044 (o)	2	Part preference, part randomised; sample size calculation req'd 152.
13 (Gijla <i>et al.</i> , 1998) [54]	RCT	Needle suspension	146/204 (56:46:44)	3y	89% vs. 80% vs. 86%; p=ns (o)	2	No ss calculation; 28% lost to FU
		Transvaginal colpo					
14 (Kammerer-Doak <i>et al.</i> , 1999) [35]	RCT	Ant. colporrhaphy	35/35 (19:16)	1y	89% vs. 31% (o) RR 0.15 (95% CI 0.04 to 0.59)	2	Ant. colporrhaphy in 16% vs. 100%; paravaginal repair in 42% vs. 6%. No ss calculation
15 (Quadri <i>et al.</i> , 1999) [49]	RCT	MMK	30/30 (15:15)	1y	53% vs. 93%; p=0.017 (o)	2	No ss calculation.
16 (Colombo <i>et al.</i> , 2000) [37]	RCT	Ant. colporrhaphy	68/71 (35:33)	≥8y	74% vs. 42% (o) OR 3.9 (95% CI 1.3 to 12.5), p=0.02	2	Vag. or abdo. hysterectomy also done; post repair in 100% vs. 34%
17 (Sand <i>et al.</i> , 2000) [57] (Culligan <i>et al.</i> , 2003) [59]	RCT	Slings (Gore-tex)	28,36/37 (19:17)	3m/33-116m	90% vs. 100%; p=ns (o - 3m) 85% vs. 100%; p=ns (o - longer-term)	2	Only 28 in longer-term FU; concurrent procedures in 21% vs. 12%
18 (Fatthy <i>et al.</i> , 2001) [70]	RCT	Lap colpo	74/74 (40:34)	18m	85% vs. 88%; p=ns (o+s)	2	No ss calculation.
19 (Demirci & Yucei, 2001) [58]	Quasi-RCT	Slings (rectus fascia)	34/46 (17:17)	1y	88% vs. 94%; RR 2.00; 95% CI 0.20, 20.04 (o)	2	Quasi-RCT - by alternation. No ss calculation; analysis not clear if ITT.
20 (Cheon <i>et al.</i> , 2003) [71]	RCT	Lap colpo	90/90 (43:47)	1y	86% vs. 85%; p=ns (o)	2	37% vs. 15% underwent concomitant hysterectomy
21 (Ankardal <i>et al.</i> , 2005) [72]	RCT	Lap colpo (sutures) Lap colpo (mesh)	184/211 (63:49:72)	1y	92% vs. 90% vs. 63% (o) p<0.05 open vs. mesh	2	Unclear randomisation; all pts randomised to Burch or lap colpo (mesh) also included in separate multicentre study (Ankardal <i>et al.</i> , 2004). Only completers analysed.
22 (Ustun <i>et al.</i> , 2005) [73]	RCT	Lap colpo	52/52 (26:26)	3-24m	81% vs. 81%; p=ns	2	Many concurrent procedures - varied between groups

**Table 2. Published level 1 & 2 evidence relating to open colposuspension for the treatment of stress urinary incontinence (Continued) Notes: patient numbers are given as – total no. followed up or analysed /total no. recruited (no. in comparator group) SS = sample size; ITT = intention to treat**

	Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj)/ effect size	EL	Comments
23	(McCreary & Thompson, 2005) [50]	RCT	MMIK	138/? (66:72)	6-60m	59% vs. 49%; p=0.02 (s+o)	2	No. randomised not clear, all had concurrent paravaginal repair.
24	(Ward et al., 2002) [65] (Ward et al., 2004) [67] (Ward et al., 2008) [45] (Manca et al., 2003) [134]	RCT	TVT	316/344 (146:170)	6m, 2y, 5y	57% vs. 66%; (95% CI for diff. -4.7%, +21.3%) (missing = fail) (o at 6m) 81% vs 80% (OR 1.67, 95% CI 0.59 to 2.06) (o at 2y) – completers analysis 81% vs 90% (OR 0.47, 95% CI 0.16 to 1.4) (o at 5y) – completers analysis Best and worst case 5y cure rates in sensitivity analysis 33%–82% TVT, 26%–90% colposuspension.	1	8% dropout after randomisation before surgery (colpo>TVT). 88% FU at 6m, 71% at 2y and 51% at 5y.
25	(Liapis et al., 2002) [64]	Quasi-RCT	TVT	71/71 (36:35)	2y	84% vs. 86%; p=ns (o)	2	Quasi-RCT – alternation; no ss calculation
26	(Wang & Chen, 2003) [66]	RCT	TVT	90/108 (41/49)	12-36m	82% vs. 76%; p=ns (o)	2	SS calculated on obstructive outcome rather than cure.
27	(El-Barky et al., 2005) [68]	RCT	TVT	50/50 (25:25)	3-6m	72% vs. 72%; p=ns (s)	2	Randomisation not stated, analysis not clear if ITT. No ss calculation
28	(Bai et al., 2005) [60]	RCT	TVT	92/92 (33:31:28)	1y	88% vs. 87% vs. 93%; p<0.05 for sling vs. others	2	Disparities between text and tables. No ss calculation
29	(Kitchener et al., 2006) [74] (Dumville et al., 2006) [44]	RCT	Sling (rectus fascia) Lap colpo	242/291 (147:144)	2y	70% vs. 80% (o)	1	5 had no op., & 12 changed op. after randomis'n. Objective data on 83%.
30	(Carey et al., 2006) [43]	RCT	Lap colpo	164/200 (88:76)	3-5y	78% vs. 72%; p=0.22 (o at 6m) 80% vs. 69%; p=0.38 (s at 2y)	2	Telephone interview at 3-5y; results 'similar' to 24m
31	(Tennstedt & Urinary Incontinence Treatment Network, 2005) [61] (Albo et al., 2007) [46] (Richter et al., 2008) [63]	RCT	Sling (rectus fascia)	520/655 (329:326)	2y	49% vs. 66% (p<0.001) (s+o)	1	50% concomitant surgery for POP; 79% outcome assessment at 2 years.
32	(Sivasiloglu et al., 2007) [47]	RCT	TOT	63, 100/100 (51:49)	1y & 2y	80% vs. 86%; p=0.4 (o at 1y) 84% vs. 88%; p=0.6 (o at 2y)	2	No ss calculation. Only 63 FU at 2y

Collaborating Centre for Women's & Children's Health, 2006) identified two further RCTs comparing MMK with open colposuspension (Quadri *et al.*, 1999, McCrery & Thompson, 2005) [49,50]. We have not identified other level 1 or 2 evidence relating to MMK (see table 3). The Cochrane review found that whilst results at early follow-up were not significantly different, both subjective and objective cure were significantly better after the Burch procedure than after MMK at one to five years after surgery (RR 0.44; 95%CI 0.25 to 0.77) (Lapitan *et al.*, 2005) [17] [EL=1]. One of the additional studies identified in the review underlying the NICE guidance showed significantly better subjective and objective results from MMK at 1 year (negative stress test 93% vs. 53%;  $p=0.02$ ) (Quadri *et al.*, 1999) [49] [EL=2]; the other showed significantly better subjective outcomes from colposuspension at a mean follow-up of 2 years (59% vs. 49%;  $p=0.02$ ) (McCrery & Thompson, 2005) [50] [EL=2]; neither reported longer term outcome.

Other longer term follow up data are limited, and of poor quality. Six studies looking specifically at long-term outcome found cure rates averaging 58% at periods between 4 and 15 years (McDuffie *et al.*, 1981, Colombo *et al.*, 1998, Czaplicki *et al.*, 1998, Luna *et al.*, 1999, Hegarty *et al.*, 2001, Demirci *et al.*, 2002) 85-90. Two studies showing trends over time in 204 and 81 patients respectively reported cure in 90% and 77% at one year, 86% and 57% at five years, and 72% and 28% at 10 years (McDuffie *et al.*, 1981, Czaplicki *et al.*, 1998) [85,87] [EL=3].

**Summary:**

Although short-term results indicate comparable cure rates to colposuspension, there is limited evidence that longer-term outcome is poorer following MMK [EL=1], and declines further over time [EL=3]. The previous edition of this consultation found no reason to support the continued use of MMK over colposuspension; there is no new evidence to indicate a change in this view.

**Recommendation:**

**The MMK procedure is not recommended for the treatment of SUI. [Grade A]**

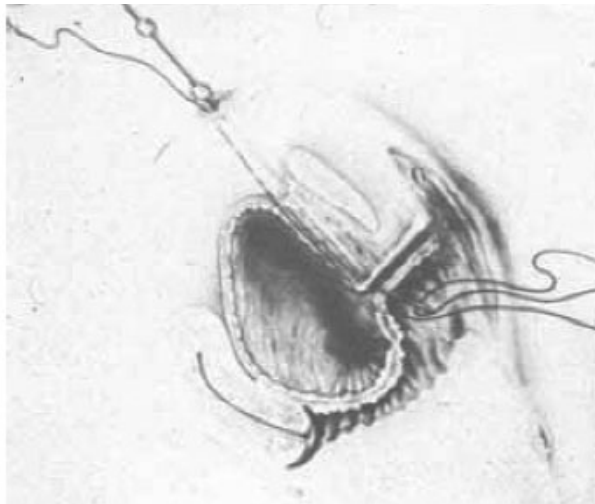
**e) Needle suspension procedures (Figure 3)**

Several endoscopic and non-endoscopic bladder neck needle suspension procedures have been described since the original report of Pereyra (Pereyra, 1959) [91]; modifications include those described by Stamey (Stamey, 1973) [92], Gittes (Gittes & Loughlin, 1987) [93], and Raz (Raz *et al.*, 1992) [94]. The procedures have been considered appropriate for either primary or recurrent SUI in particular where open retropubic suspension procedures were unsuitable, such as in frail or elderly women or where colposuspension may be technically difficult because of poor vaginal mobility

**Table 3. Published level 1 & 2 evidence relating to Marshall-Marchetti-Krantz procedure for the treatment of stress urinary incontinence**  
**Notes: patient numbers are given as –no. followed up or analysed /total no. recruited (analysed no. in comparator group)**  
**SS = sample size; ITT = intention to treat**

Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj)/ effect size	EL	Comments
1 (Henriksson & Ulmsten, 1978) [84]	Quasi-RCT	Sling (Zoedler, vaginal)	30/30 (15:15)	3m	100% vs. 100% (o)	2	Quasi-RCT - by alternation. No ss calculation; analysis not clear if ITT.
2 (Liapis <i>et al.</i> , 1996b) [33]	RCT	Colposuspension Ant. colporrhaphy	161/170 (51:54:50)	5y	67% vs. 89 vs. 56% (o) $p<0.001$ colposuspension vs. others	2	Apparent overlap with (Liapis <i>et al.</i> , 1996a); latter describes 2 arms at 3 years, this 3 arms at 5 years.
3 (Colombo <i>et al.</i> , 1994) [48] (Colombo <i>et al.</i> , 1998) [86]	RCT	Colposuspension	80/80 (40:40)	2-7y	65% vs. 80%; $p=ns$ (o)	2	Wide range of FU times (differed between groups). No ss calculation
4 (Quadri <i>et al.</i> , 1999) [49]	RCT	Colposuspension	30/30 (15:15)	1y	93% vs. 53%; $p=0.017$ (o)	2	No ss calculation.
5 (McCrery & Thompson, 2005) [50]	RCT	Colposuspension	138/? (72:66)	6-60m	49% vs. 59%; $p=0.02$ (s+o)	2	No. randomised not clear; all had concurrent paravaginal repair.





**Figure 3 : The Stamey needle colposuspension**

or capacity, from atrophic change, previous surgery, or radiotherapy.

The review by Jarvis was based largely on low level evidence, with only seven out of the 213 surgical studies reviewed being randomised. He identified data from 3553 women undergoing endoscopic or non-endoscopic bladder neck needle suspension with an average subjective cure rate of 79% and objective cure rate of 71% (Jarvis, 1994) [20] [EL=2].

The Cochrane review of needle suspension procedures (Glazener & Cooper, 2004) [15] and the systematic review underlying the NICE guideline on urinary incontinence (National Collaborating Centre for Women's & Children's Health, 2006) both included the same ten RCTs describing six different needle suspension procedures, 1983, (Palma *et al.*, 1988, Bergman *et al.*, 1989a, Bergman *et al.*, 1989b, Hilton, 1989, Stein & Weinberg, 1991, German *et al.*, 1994, Bergman & Elia, 1995, Athanassopoulos & Barbalias, 1996, Gilja *et al.*, 1998, Klutke *et al.*, 1999, Di Palumbo, 2003) [95,28,29,96,29,97,52,30,53,54,36,39]. We did not identify any more recent high level evidence relating to this group of procedures (see Table 4). No studies were identified comparing needle suspension with sham treatment or non-surgical treatments; one small study compared with a sling procedure, seven with colposuspension, and three with anterior repair; two others compared different needle suspension procedures or different sutures. The needle suspension procedures were found to be less effective than colposuspension based on subjective outcome within one year of surgery (RR for failure 1.70, 95% CI 1.11 to 2.60); and after the first year (29% vs. 16% failure; RR for failure 2.00, 95% CI 1.47 to 2.72); there were no clear differences between the procedures for any of the other outcome measures examined, although the confidence estimates around estimates were wide. The performance of needle suspension and anterior colporrhaphy appeared similar

in terms of subjective cure rates after 12 months (RR 0.86, 95%CI 0.64 to 1.16) and voiding dysfunction, whether the women had prolapse in addition to stress incontinence or not [EL=1].

Only low level evidence is available to judge long-term outcomes. Cure rates of 31%-68% have been reported at 4-5 years (Hilton & Mayne, 1991, Bergman & Elia, 1995, Reid & Parys, 2005) [98,30,99] and 20%-33% at 10 years (Trockman *et al.*, 1995, Mills *et al.*, 1996) [100,101]. Unpublished results from the Leeds group showed 80% cures at 1 year ( $n=186$ ), declining to 45% at 2 years, 18% at 4 years, and to only 6% at 10 years ( $n=17$ ) (Jarvis *et al.*, 1999) [21] [EL=3].

A later development of the needle suspension procedures, introduced in an attempt to improve the longevity of results, was the use of bone anchors for the suspensory sutures. Bone-anchored cystourethropexy has not been subject to RCT, although two versions, the 'Vesica®' and 'In-Tac®' procedures, have been reviewed by the NICE Interventional Procedures Programme (National Institute for Health & Clinical Excellence, 2003). They highlighted the poor long-term outcomes, and concluded that current evidence of the safety and efficacy of bone-anchored cystourethropexy is not adequate to support the use of this procedure in routine clinical practice [EL=2].

Although we found no new high level evidence regarding needle suspension procedures, there is continuing concern not only about long-term efficacy, but also about long-term complications which continue to emerge. These include suture migration into the urinary tract, and chronic infective complications from the implanted buffers and/or bone anchors (Goldberg *et al.*, 2004, Gregorakis *et al.*, 2006, Smith & Rovner, 2006) [102-104]; osteomyelitis of the pubic bones has been reported to occur in 1.3% in one series (Goldberg *et al.*, 2004) [102] [EL=3].

### Summary:

High level evidence indicates that needle suspension procedures are as effective as anterior colporrhaphy, but less effective than colposuspension even in the short-term [EL=1]. Long-term studies indicate lack of longevity even of the initial modest results; long-term complications remain a concern [EL=3].

### Recommendation:

**Endoscopic and non-endoscopic bladder neck needle suspension procedures, with and without bone-anchors are not recommended for the treatment of SUI. [Grade A]**

### f) Paravaginal repair

The paravaginal defect repair was first described by White in the early part of the 20<sup>th</sup> century, as a vaginal procedure (White, 1909, 1912) [105,106]. It has since

**Table 4. Published level 1 & 2 evidence relating to Needle suspension procedures for the treatment of stress urinary incontinence. Notes: patient numbers are given as –no. followed up or analysed /total no. recruited (analysed no. in index group: analysed no. in comparator group) SS = sample size; ITT = intention to treat**

	Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj) effect size	EL	Comments
1	(Mundy, 1983) [51]	Quasi-RCT	Colposuspension	51/51(25:26)	Min 1y	Success 76% vs 88% (s)	2	Quasi-RCT - by alternation. No ss calculation; analysis not clear if ITT.
2	(Palma <i>et al.</i> , 1988) [95]	RCT	MMK	50/70 (40:30)	2-56m	50% vs. 77%; RR 2.14; 95% CI 0.98, 4.69 (o)	2	Unclear randomisation; FU duration wide & diff for 2 groups.
3	(Hilton, 1989) [96]	RCT	Sling (porcine dermis)	20/20 (10:10)	2y	80% vs. 90% (o - at 3m) 70% vs. 90% (s - at 2y)	2	Included only USI with vaginal narrowing unsuitable for colpo.
4	(Bergman <i>et al.</i> , 1989a) [28]	RCT	Colposuspension Ant. colporrhaphy	107/127 (34:38:35)	1y	65% vs. 89% vs. 63% (o) p<0.05 colposuspension vs. others	2	Data only reported for completers.
	(Bergman & Eila, 1995) [30]		Colposuspension Ant. colporrhaphy	64/78 cured at 1y above	5y	43% vs. 82% vs. 37% (o) p<0.05 colposuspension vs. others	2	Data only on those cured at 1y.
5	(Stein & Weinberg, 1991) [97]	RCT	Goretex vs. Prolene sutures	20/24 (9:11)	6m	100% vs. 73%; RR 0.17; 95% CI 0.01, 2.94 (S)	2	3 different suspension procedures in series; no ss calculation.
6	(German <i>et al.</i> , 1994) [52]	RCT	Colposuspension	50/50 (26:24)	12-44m	58% vs. 71%; 53% vs. 86% for 29 primary procedures; p<0.05	2	Randomisation not stated; analysis not clear if ITT; range of FU mean 2y.
7	(Bergman <i>et al.</i> , 1989b) [29] (Klutke <i>et al.</i> , 1999) [36]	RCT	Colposuspension Ant. colporrhaphy	298/339 (98:101:99)	1y	70% vs.87% vs.69% (o) p<0.02 colposuspension vs. others	2	All vag. hysterectomy & repair. Number randomised unclear; 339 'eligible', and 41 lost to follow-up.
8	(Athanasopoulos & Barbalias, 1996) [53]	Quasi-RCT	Colposuspension	51/51 (24:27)	8-27m	71% vs. 74%; p=ns (o)	2	Quasi-RCT – randomised by DoB. No ss calculation; analysis not clear if ITT.
9	(Gijla <i>et al.</i> , 1998) [54]	RCT	Colposuspension Transvaginal colpo	146/204 (46:56:44)	3y	80% vs. 89% vs. 86%; p=ns (o)	2	No ss calculation; 28% lost to FU
10	(Di Palumbo, 2003) [39]	RCT	Ant. colporrhaphy	80/80 (28:52)	9m-4.5y	86% vs. 73% (o); p<0.01	2	2:1 randomisation; wide range of FU

been described using either abdominal (Richardson *et al.*, 1976) [107] or laparoscopic approaches (Richardson *et al.*, 1997) [108]. There is little high level evidence on these procedures, and the available studies are often confounded by the use of combined procedures.

Only one RCT has been published which included abdominal paravaginal defect repair in a comparison with open colposuspension in women with SUI and grade 1 urethrocytocele (Colombo *et al.*, 1996) [55]. Although this study was included in the Cochrane review of colposuspension, it was felt that this study was too small, and the data insufficient to draw conclusions. Thirty six women were recruited, and although no sample size calculation is included in the paper, recruitment was terminated when it was felt no longer ethical to randomise patients. The majority of women in both groups also underwent hysterectomy and culdoplasty. At mean follow-up of about 2 years, objective (negative stress test) and subjective cure rates were significantly higher in the colposuspension group (100% versus 61%,  $p=0.004$  and 100% versus 72%,  $p=0.004$ , respectively) [EL=2].

Several small case series with limited follow-up and largely subjectively defined outcome were reviewed in the last edition of this consultation. Cure rates of 80% to 94% were found following the abdominal procedure (Scotti *et al.*, 1998, Bruce *et al.*, 1999) [109,110], 70% to 93% following the laparoscopic procedure (Ostrzenski, 1998, Miklos & Kohli, 2000) [111,112], and 43% to 89% following the vaginal procedure (Mallipeddi *et al.*, 2001, Clemons *et al.*, 2003)[113,114], [EL=3]. Only one small series has been published more recently, indicating a cure rate of 93% for prolapse and 80% for SUI in 20 women treated by abdominal paravaginal repair alone compared to cures in 100% of 10 women treated by paravaginal plus incontinence surgery, at a mean follow-up period of 40 months [EL=3].

#### **Summary:**

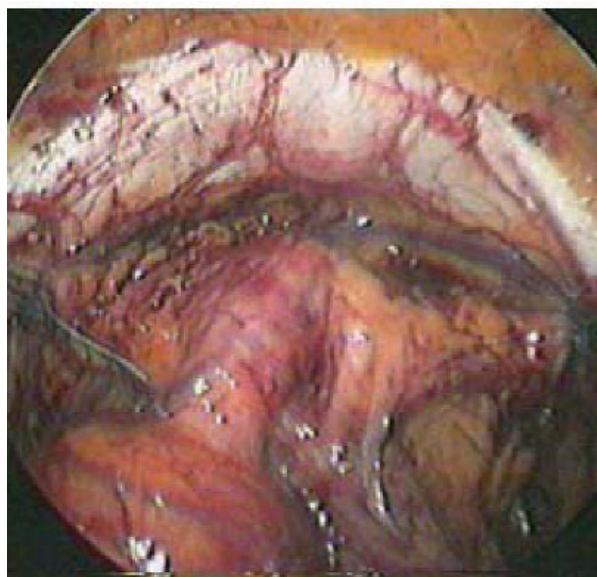
There is limited evidence that abdominal paravaginal defect repair is less effective than open colposuspension [EL=2].

#### **Recommendation:**

**Paravaginal defect repair is not recommended for the treatment of SUI alone. [Grade A]**

#### **g) Laparoscopic colposuspension (Figure 4)**

The Cochrane review of laparoscopic colposuspension has been updated since the last edition of this consultation; it now includes details of 22 RCTs that including laparoscopic colposuspension (Dean *et al.*, 2006a) [18], 14 more than their initial review (Moehrer *et al.*, 2000) [11]. Of these 22 trials, ten compared



**Figure 4 : View of a completed laparoscopic colposuspension through the laparoscope**

laparoscopic colposuspension with open colposuspension (Su *et al.*, 1997, Burton, 1999, Summitt *et al.*, 2000, Fatthy *et al.*, 2001, Morris *et al.*, 2001, Cheon *et al.*, 2003, Ankardal *et al.*, 2004, Ankardal *et al.*, 2005, Carey *et al.*, 2006, Kitchener *et al.*, 2006) [69,115,116,70,117,71,118,72,43,74], and eight with minimally invasive mid-urethral slings (Persson *et al.*, 2002, Ustun *et al.*, 2003, Maher *et al.*, 2004, Paraiso *et al.*, 2004, Valpas *et al.*, 2004, Mirosh & Epp, 2005) [119-124]; the remainder examined different aspects of the laparoscopic technique (one vs. two sutures (Persson & Wolner-Hanssen, 2000) [125], sutures vs. Mesh (Ross, 1996, Zullo *et al.*, 2001, Ankardal *et al.*, 2005) [126,127,72] and transperitoneal vs. extraperitoneal approach to laparoscopy (Wallwiener *et al.*, 1995 [128]. Seven compared laparoscopic colposuspension with Tension-free Vaginal Tape%, and these have been published separately (Dean *et al.*, 2006b) [129]. Seven were only available as abstracts at the time of the systematic review underlying the NICE guidance on urinary incontinence, and hence were not considered in their report (National Collaborating Centre for Women's & Children's Health, 2006). Eight of the ten studies comparing laparoscopic colposuspension with open colposuspension were included along with eight retrospective cohort studies in a recently published meta-analysis (Tan *et al.*, 2007) [130]. We identified two further RCTs on laparoscopic colposuspension (Piccione *et al.*, 2001, Ustun *et al.*, 2005) [131,73]; in addition one study previously only in abstract form has recently been published (Carey *et al.*, 2006) [43], and two have further publications with longer-term follow-up (Jelovsek *et al.*, 2008) [132] or cost-effectiveness data (Valpas *et al.*, 2006) [133]. Details of the 15 published studies (22 papers) are given in **table 5**.

**Table 5. Published level 1 & 2 evidence relating to laparoscopic colposuspension for the treatment of stress urinary incontinence Notes: patient numbers are given as – total no. followed up or analysed /total no. recruited (no. in index group: no. in comparator group) SS = sample size; ITT = intention to treat**

Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj)/ effect size	EL	Comments
1 (Waltwiener et al., 1995) <sup>28</sup>	RCT	Transperitoneal vs. extraperitoneal	22 (? : ?)	1-12m	92% (s+o)	2	Mixture of suturing/stapling techniques; outcomes not separately evaluable.
2 (Ross, 1996) <sup>26</sup>	RCT	Sutures vs. mesh/staples	69/69 (35:34)	1y	91% vs. 94%; RR 0.97; 95% CI 0.85, 1.11	2	
3 (Su et al., 1997) <sup>89</sup>	RCT	Open colpo	92/92 (46:46)	6m	80% vs. 96%; p=0.044 (o)	2	Part preference, part randomised; sample size calculation req'd 152.
4 (Persson & Wolner-Hanssen, 2000) <sup>425</sup>	RCT	2 single bite vs. 1 double bite sutures	161/? (83:78)	1y	83% vs. 58%; p<0.001	2	Enrolment curtailed early after interim analysis
5 (Piccione et al., 2001) <sup>31</sup> (Zullo et al., 2001) <sup>27</sup> (Zullo et al., 2002) <sup>603</sup> (Zullo et al., 2004) <sup>604</sup>	RCT	Sutures vs. mesh/staples	53/60 (27:26)	1 & 3y	89% vs. 75% (o - at 1y) 70% vs. 42% (o - at 2y) 58% vs. 38% (o - at 3y); p<0.05	2	Only completers analysed in 2001 paper; ITT used in 3 year follow-up.
6 (Fatthy et al., 2001) <sup>90</sup>	RCT	Open colpo	74/74 (34:40)	18m	88% vs. 85%; p=ns (o+s)	2	No ss calculation.
7 (Persson et al., 2002) <sup>19</sup>	RCT	TVT	68/79 (31:37)	1y	87% vs. 89% RR 0.98; 95% CI 0.82, 1.16	2	270 approached; 79 randomised. Study designed to examine costs.
8 (Cheon et al., 2003) <sup>1</sup>	RCT	Open colpo	90/90 (47:43)	1y	85% vs. 86%; p=ns (o)	2	15% vs. 37% underwent concomitant hysterectomy
9 (Ustun et al., 2003) <sup>20</sup>	RCT	TVT	46/46 (23:23)	3-24m	83% vs. 83%; RR1.00; 95% CI 0.77, 1.30 (s+o)	2	No information on randomisation; no allowance for variation in FU
10 (Valpas et al., 2003) <sup>905</sup> (Valpas et al., 2004) <sup>123</sup> (Valpas et al., 2006) <sup>133</sup>	RCT	TVT	121/128 (51:70)	1y	57% vs. 86% (95% CI for diff. 12.7, 43.9); p=0.000 (o)	2	Lap. colpo with mesh. SS calculation required 176.



**Table 5. Published level 1 & 2 evidence relating to laparoscopic colposuspension for the treatment of stress urinary incontinence Notes: patient numbers are given as – total no. followed up or analysed /total no. recruited (no. in index group: no. in comparator group) SS = sample size; ITT = intention to treat**

Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj)/ effect size	EL	Comments
11 (Paraiso <i>et al.</i> , 2004) <sup>22</sup> (Jelovsek <i>et al.</i> , 2008) <sup>132</sup>	RCT	TVT	71/72 (35:36)	12- 43m  12- 88m	97% vs 81% (o – at median 18m)  43% vs. 52% (s – at median 65m)	2	SS 130; recruitment stopped early because of slow recruitment.  63 (88%) FU at 1y; 33 (46%) at 2y
12 (Ankardal <i>et al.</i> , 2005) <sup>72</sup>	RCT	Open colpo  Lap colpo (mesh)	184/211 (49:63:72)	1y	90% vs. 92% vs. 63% (o) p<0.05 open vs. mesh	2	Unclear randomisation; all pts randomised to Burch or lap colpo (mesh) also included in separate multicentre study (Ankardal <i>et al.</i> , 2004). Only completers analysed.
13 (Ustun <i>et al.</i> , 2005) <sup>3</sup>	RCT	Open colpo	52/52 (26:26)	3-24m	81% vs. 81%; p=ns	2	Many concurrent procedures - varied between groups
14 (Kitchener <i>et al.</i> , 2006) <sup>74</sup> (Dumville <i>et al.</i> , 2006) <sup>44</sup>	RCT	Open colpo	242/291 (144:147)	2y	80% vs. 70% (o)	1	5 had no op. & 12 changed op. after randomis'n. Objective data on 83%.
15 (Carey <i>et al.</i> , 2006) <sup>33</sup>	RCT	Open colpo	164/200 (76:88)	3-5y	72% vs. 78%; p=0.22 (o at 6m)  69% vs. 80%; p=0.38 (s at 2y)	2	Telephone interview at 3-5y; results 'similar' to 24m

Studies included in the Cochrane review had different lengths of follow-up, although eight studies had follow-up in the region 6 to 18 months. In comparison with open colposuspension they found subjective cure rates to range from 58% to 96% in the open and 62% to 100% in the laparoscopic group within the 18 months follow up, with a non-significant 5% lower relative subjective cure rate for laparoscopic colposuspension (RR 0.95, 95% CI 0.90 to 1.00) (Dean *et al.*, 2006a) [18] [EL=1]. The two studies with follow-up at five years or beyond unfortunately remain unpublished and available in abstract form only. Both these studies were relatively small, and their results are inconsistent, one finding better subjective outcome from the laparoscopic procedure (Morris *et al.*, 2001) [117], and one favouring the open procedure (Burton, 1999) [117]; the methodology of this latter study in particular has been questioned [EL=2].

Overall, the objective cure rate as judged by cough stress testing or pad test within 18 months was statistically significantly lower following laparoscopic colposuspension (RR 0.91, 95%CI 0.86 to 0.96) [EL=1]. Between 18 months and five years there was no significant difference (RR 1.01, 95% CI 0.88 to 1.16); again however, there was heterogeneity with one small trial greatly favouring open procedure (Burton, 1999) [115] and the other favouring laparoscopic (Morris *et al.*, 2001) [117] [EL=2]. When objective cure was judged by urodynamic investigations there was a significantly higher success rate following open colposuspension (RR 0.91, 95%CI 0.85 to 0.99).

Cost effectiveness was assessed in only one trial (Dumville *et al.*, 2006, Kitchener *et al.*, 2006) [44,74]. This study showed that whilst laparoscopic surgery produced greater quality adjusted life years (QALYs), there was an additional cost when compared to open surgery. The differential mean cost was GB£ 372 (95% credibility interval [CrI]: 274–471), and at 6 months QALYs were slightly higher in the laparoscopic arm relative to the open arm (0.005; 95% CrI: –0.012 to 0.023). The cost of each additional QALY in the laparoscopic group or incremental cost-effectiveness ratio (ICER) was £74,400 at 6 months, but reduced to £9,300 by 24 months, in view of a further increase in QALYs, but no additional costs (assumed) (Dumville *et al.*, 2006) [44] [EL=1]. Earlier studies have shown TVT™ to be dominant in cost effectiveness terms over both open (Manca *et al.*, 2003) [134] and laparoscopic colposuspension (albeit using a mesh technique) (Valpas *et al.*, 2006) [133] [EL=1].

In comparison with minimally invasive mid-urethral slings there was no statistically significant difference in subjective cure rates within 18 months (RR 0.91, 95% CI 0.80 to 1.02) [EL=1]. The definition of objective cure varied widely between studies, although overall

the objective cure rate was higher for minimally invasive mid-urethral slings than laparoscopic colposuspension (RR 0.92, 95% CI 0.85 to 0.99) [EL=1].

Studies comparing different laparoscopic techniques found that two sutures either side of the bladder neck resulted in higher subjective (RR 1.37, 95% CI 1.14 to 1.64) and objective (RR 1.42, 95% CI 1.14 to 1.77) cure rate than one (Persson & Wolner-Hanssen, 2000) [125] [EL=2], and that sutures resulted in higher subjective (RR 1.28, 95% CI 1.11 to 1.47) and objective (RR 1.20, 95%CI 1.07 to 1.35) cure rate than mesh (Ross, 1996, Piccione *et al.*, 2001, Zullo *et al.*, 2001, Ankardal *et al.*, 2005) [126,131,127,72] [EL=1].

The conclusion from the Cochrane review was that the currently available evidence suggests that laparoscopic colposuspension may be as effective as open colposuspension two years postoperatively (Dean *et al.*, 2006a) [18]. The systematic review specific to laparoscopic colposuspension and TVT™ concluded that the evidence so far appears to favour the latter as the minimal-access technique of choice for USI (Dean *et al.*, 2006b)[129]. In both cases however the authors indicated that the place of laparoscopic colposuspension in clinical practice could not be clearly defined without further long-term results.

It should also be noted that much of the published research in this area is from individuals with enthusiasm and skill in laparoscopic surgery; their results should not necessarily be seen as being generalisable to the urogynaecological/urological community at large. The NICE guidance includes amongst its recommendation that laparoscopic colposuspension is not recommended as a routine procedure for the treatment of SUI in women, but that the procedure should be performed only by an experienced laparoscopic surgeon working in a multidisciplinary team with expertise in the assessment and treatment of UI (National Collaborating Centre for Women's & Children's Health, 2006, National Institute for Health & Clinical Excellence, 2006b); this same point is emphasised in the meta-analysis from Tan and colleagues (Tan *et al.*, 2007) [130] [EL=4].

### **Summary:**

Laparoscopic colposuspension shows comparable subjective outcome, but poorer objective outcome than both open colposuspension and TVT™ in the short to medium term; longer term outcomes are unknown [EL=2]. It may not be good value for money when compared with open colposuspension in the short term (i.e. first 6 months following surgery), but it could be a cost-effective alternative over 24 months [EL=1]; other comparisons however suggest that minimally invasive mid-urethral tape procedures may be dominant in health economic terms.

## Recommendations:

**Laparoscopic colposuspension is not recommended for the routine surgical treatment of SUI in women. [Grade A]**

**Laparoscopic colposuspension might be considered for the treatment of SUI in women who also require concurrent laparoscopic surgery for other reasons. [Grade D]**

**Laparoscopic colposuspension should only be carried out by surgeons with specific training, expertise and appropriate workload in laparoscopic surgery and in the assessment and management of urinary incontinence in women. [Grade D]**

### h) Urethral bulking agents

Urethral bulking agents have been used for the treatment of SUI in women for the past 3 decades. A variety of substances have been reported to be safe and effective in this context including bovine glutaraldehyde cross linked (GAX) bovine collagen (Contigen®), polytetrafluoroethylene (Teflon®), polydimethyl-siloxane elastomer (Macroplastique®), porcine dermal implant (Permacol®), carbon-coated zirconium beads (Durasphere®), non-animal stabilized hyaluronic acid/dextranomer NASHA/Dx (Zuidex®), calcium hydroxylapatite (CaHA; Coaptite®), ethylene vinyl alcohol (Uryx®; Tegress®) and autologous tissues such as fat, chondrocytes, and myoblasts. Each of these different agents has variable biophysical properties that influence tissue compatibility, tendency for migration, radiographic density, durability and safety. The ideal urethral bulking agent has not yet been identified.

Most urethral bulking agents are injected trans-urethraly or periurethraly, in a retrograde fashion under direct cystoscopic guidance although implantation devices have been developed which potentially obviate the need for this. There is no universally accepted injection route, technique, equipment or anaesthetic regimen. The optimal location for injection has not been defined and reported injection locations have included anywhere between the mid-urethra and the bladder neck. The optimal volume of material for injection during a single session, ideal site orientation for injection, or the optimal number of reinjection sessions for any given agent (until clinical "failure" has been determined) has not been defined. Long term success may not correlate with the endoscopic appearance at the conclusion of the injection session or certain preoperative urodynamic parameters.

The exact mechanism by which urethral bulking agents exert their effects on continence has not been defined although an obstructive effect or an improved hermetic

effect has been suggested (Dmochowski & Appell, 2000) [135]. Although initially it was thought that urethral bulking agents would be most effective in patients with intrinsic sphincter deficiency (ISD) alone, subsequent reports have suggested clinical efficacy in patients with urethral hypermobility (Herschorn *et al.*, 1996, Steele *et al.*, 2000, Bent *et al.*, 2001) [136,137,138].

The Cochrane review of periurethral injection therapy has been updated since the last edition of this consultation (Keegan *et al.*, 2007) [19] and now includes 12 RCTs including bulking agents in at least one arm; this is five additional trials over the previous review (Pickard *et al.*, 2003) [14], although five do not exist as full peer-reviewed publications and are available only as conference abstracts. One double blind study compared autologous fat with a placebo (Lee *et al.*, 2001) [139]. Two studies compared injection with open surgery; one collagen therapy with bladder neck suspension, sling or Burch colposuspension (Corcos *et al.*, 2005) [140], the other silicon particles with pubovaginal sling (Maher *et al.*, 2005) [141]. Eight studies compared two different bulking agents; two compared GAX collagen with silicon particles (Macroplastique®) (Anders *et al.*, 2002, Appell *et al.*, 2005) [142,143]; two compared GAX collagen with carbon particles (Durasphere®) (Lightner *et al.*, 2001, Andersen, 2002) [142,145] two compared with calcium hydroxylapatite (Coaptite®) , coaptite with collagen (Dmochowski *et al.*, 2002a, Appell *et al.*, 2005) [146,143]; one study compared GAX collagen with ethylene vinyl alcohol (Uryx®) (Dmochowski *et al.*, 2002b) [147]; a single study compared porcine dermal implant (Permacol®) with silicone injection (Macroplastique®) (Bano *et al.*, 2005) [148]; and one study compared periurethral and transurethral injection techniques (Schulz *et al.*, 2004) [149]. We identified only one further RCT comparing calcium hydroxylapatite with bovine dermal collagen (Mayer *et al.*, 2007) [150] (see table 6).

The Cochrane group felt the available trials were small, generally of only moderate quality, and the limited data available were not suitable for meta-analysis in view of the wide confidence intervals around all estimates.

The study comparing urethral bulking using autologous fat with a saline placebo (Lee *et al.*, 2001) [139] found cure or improvement in 21% in both groups 3 months after the final injection (RR 0.98; 95% CI 0.75 to 1.29), with no significant change from baseline in UI score or in pad weight. One woman died from fat embolism [EL=1].

The two studies comparing urethral bulking with conventional surgery found significantly better objective outcome in the surgical groups, although not in subjective cures or patient satisfaction (Corcos *et al.*, 2005, Maher *et al.*, 2005) [140,141] [EL=2].

**Table 6. Published level 1 & 2 evidence relating to urethral bulking agents for the treatment of stress urinary incontinence Notes: patient numbers are given as – total no. followed up or analysed /total no. recruited (no. in index group: no. in comparator group) SS = sample size; ITT = intention to treat**

	Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj)/ effect size	EL	Comments
1	(Lee et al., 2001) [139]	DB-RCT	Autologous fat vs. Placebo (saline)	68/68 (35:33)	3m	22% vs. 21%; p=ns (s)	2	Re-injection up to 3xmonthly
2	(Lightner et al., 2001) [144]	DB-RCT	Carbon coated zirconium beads (Durasphere) vs. Bovine collagen (Contigen)	235/355 (115:120)	9-30m	37% vs. 35%; p=ns (s)	2	33% lost to FU; only completers analysed.
3	(Andersen, 2002) [145]	RCT	Carbon coated zirconium beads (Durasphere) vs. Bovine collagen (Contigen)	46/52 (25:21)	18-36m	40% vs. 14%; p=ns (s)	2	Both injected transurethral. No information on randomisation, allocation concealment, or blinding.
4	(Schulz et al., 2004) [149]	RCT	Transurethral vs. Periurethral injection of hyaluronic acid /dextran copolymer (Zuidex)	34/40 (17:17)	12m	3/17 (18%) vs. 1/17 (6%); p=ns (s)	2	R e-injection up to 3xmonthly. 20 pts terminated study early owing to recurrent or persistent UI.
5	(Bano et al., 2005) [148]	RCT	Silicone particles (Macroplastique) vs. Porcine dermal collagen (Permacol)	48/50 (25:25)	6m	38% vs. 60%	2	Silicone transurethral; collagen largely periurethral. No details of randomisation; unclear whether ITT analysis used; No statistical analysis reported.
6	(Maher et al., 2005) [141]	RCT	Silicone particles (Macroplastique) vs. Sling (rectus fascia)	45/45 (23:22)	6m	9% vs. 81%; p<0.0001	2	Silicone injected transurethral.
7	(Corcos et al., 2005) [140]	RCT	Surgery (left to surgeon's choice & experience)	133 (66:67)	12m	52% vs. 55%; mean difference: -3.71% (95% CI -20.61, +13.2); p=ns	2	Glutaraldehyde cross-linked (GAX) collagen; up to 3 injs at 1month intervals. 15 withdrew after randomisation; ITT analysis
8	(Mayer et al., 2007) [150]	SB-RCT	Calcium hydroxylapatite (Coaptite) vs. Bovine dermal collagen (Contigen)	231/296 (131:100)	12m	83 (63.4%) vs. 57 (57%) improved by 1 Stamey grade; p=0.34 (s)	2	22% lost to FU; unclear assignment numbers; limited outcomes; improvement only, no measure of 'cure'. Up to 5 injs over 6m.



All results from studies comparing different agents had wide confidence intervals. Silicone particles (Anders *et al.*, 2002, Ghoniem *et al.*, 2005) [142,151], calcium hydroxylapatite (Dmochowski *et al.*, 2002a, Appell *et al.*, 2005, Mayer *et al.*, 2007) [146,143,150], ethylene vinyl alcohol (Dmochowski *et al.*, 2002b) [147], and carbon spheres (Lightner *et al.*, 2001, Andersen, 2002) [144,145] gave improvements equivalent to collagen [EL=2]. Porcine dermal implant gave improvements comparable to silicone at six months (Bano *et al.*, 2005) [148] [EL=2]. A comparison of periurethral and transurethral methods of delivery of the bulking agent found similar outcome but a higher rate of early complications in the periurethral group (Schulz *et al.*, 2004) [149] [EL=1].

Many published case series exist in the literature describing each of the bulking agents mentioned here; 50 of these are reviewed in the systematic review forming the basis of the NICE guidance (National Collaborating Centre for Women's & Children's Health, 2006, National Institute for Health & Clinical Excellence, 2006b). The methodological problems surrounding these are even greater than those of the RCTs described, and they provide little useful additional data to inform practice.

Several periurethral bulking agents have been associated with the formation of periurethral pseudocysts (Abdelwahab & Ghoniem 2007., Hartanto *et al* 2003., Sweat & Lightner 1999., Petrou *et al* 2006., Hagemeyer *et al* 2006., Madjar *et al* 2006) [152,153,154,155,156,157]. These collections may result in a variety of symptoms including pain, voiding dysfunction and urinary retention. Definitive treatment consists of transurethral resection, transvaginal needle aspiration or transvaginal resection.

**Summary:**

The evidence of benefit from urethral bulking agents is limited, and appears to be short-term. The only placebo controlled randomised study found similar symptomatic improvement with both placebo and autologous fat [EL=1]. Greater symptomatic improvement was observed after conventional surgery, although these advantages may need to be seen against likely higher risks [EL=2]. There is no evidence that any one bulking agent has advantage over any other [EL=2]. There are no available data comparing urethral bulking agents with non-surgical treatments or with other minimal access surgical techniques.

**Recommendations:**

**If urethral bulking agents are to be used, women should be made aware that repeat injections are likely to be required to achieve efficacy, that efficacy diminishes with time, and is inferior to that of conventional surgical techniques; they should also be aware of alternative minimally invasive procedures. [Grade B] Newly developed**

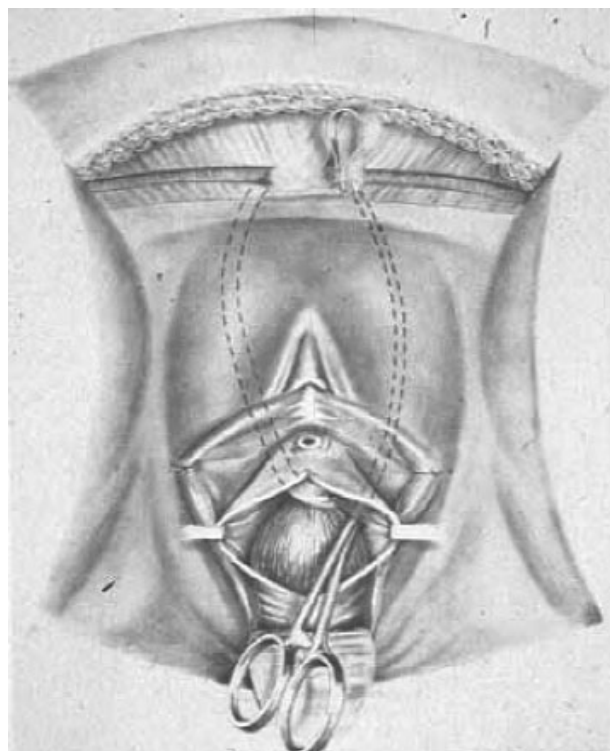
**materials for consideration as urethral bulking should be subject to robust evaluation by appropriately powered well designed RCT with long-term follow-up before widespread introduction into clinical practice. [Grade D]**

**i) 'Traditional' sling procedures (Figure 5)**

The term 'traditional' sling procedures is used here, in line with the terminology used in the latest Cochrane review, (Bezerra *et al.*, 2005) [16] to distinguish open sling procedures more usually placed at the region of the bladder neck, from the newer minimal access mid-urethral tape procedures.

Sling procedures have been in use since the beginning of the twentieth century. Many variations in the technique have been described although it is unclear which of these materially influence the outcome. The majority of sling procedures have involved a combined abdomino-vaginal approach, although totally abdominal procedures are described. Suspended or 'sling on a string' methods have been developed in order to reduce the invasiveness of the procedure, and to shorten the length of sling material. As with needle suspension procedures, bone anchoring has been used as an alternative form of sling suspension.

Sling materials vary widely, and whilst perhaps having only limited effect on initial efficacy, may have considerable impact on the longevity of procedures,



**Figure 5 : The Aldridge sling employing rectus sheath fascia**

or the associated morbidity. Materials may be synthetic or biological; the latter include autograft (rectus fascia, fascia lata, round ligament, dermis, vaginal skin, and gracilis, levator, and rectus muscles), allograft (fascia, dermis and dura mater) and xenograft (porcine dermis and small intestinal mucosa, bovine fascia and pericardium). Both biological and synthetic sling materials are analysed together in the Cochrane review, although these were considered separately in the systematic review underlying the NICE guidance on urinary incontinence (National Collaborating Centre for Women's & Children's Health, 2006, National Institute for Health & Clinical Excellence, 2006b). NICE has also published a non-systematic review of biological sling procedures under its Interventional Procedures Programme (National Institute for Health & Clinical Excellence, 2006a).

The Cochrane review included 13 RCTs describing a total of 760 women of whom 627 were treated with sub urethral slings; four of these are available only in abstract form and remain unpublished as full peer-reviewed papers. Five of the trials compared sub urethral slings with open abdominal retropubic suspension (Henriksson & Ulmsten, 1978,ENZELSBERGER *et al.*, 1996, Sand *et al.*, 2000, Demirci & Yucel, 2001, Fischer *et al.*, 2001) [84,56-58,158], and one compared sub urethral slings with Stamey needle suspension (Hilton, 1989) [96]. In six trials, different types of sub urethral sling were compared with each other (Barbalias *et al.*, 1997, Lucas *et al.*, 2000, Shin *et al.*, 2001, Arunkalaivanan & Barrington, 2003, Kondo *et al.*, 2003, Viseshsindh *et al.*, 2003) [159-164]. Nine different sling materials were included (Teflon, polytetrafluoroethylene, prolene, porcine dermis, lyophilised dura mater, fascia lata, vaginal wall, autologous dermis and rectus fascia). There were no comparisons of sub urethral sling with anterior repair, laparoscopic retropubic suspension, urethral bulking agents or artificial urinary sphincter. One trial compared surgery (including slings) with anticholinergic medication. The systematic review underlying the NICE guidance on urinary incontinence (National Collaborating Centre for Women's & Children's Health, 2006, National Institute for Health & Clinical Excellence, 2006b) included three further RCTs comparing pubovaginal sling with TVT ((Lucas *et al.*, 2004, Bai *et al.*, 2005, Wadie *et al.*, 2005) [165,60,166] and open colposuspension (Bai *et al.*, 2005) [60], or other sling procedures (Lucas *et al.*, 2004) [165]. We identified a further publication of longer-term outcomes from one of the included RCTs (Guerrero *et al.*, 2007) [167] and one new study (Tennstedt & Urinary Incontinence Treatment Network, 2005, Albo *et al.*, 2007, Mallett *et al.*, 2008, Richter *et al.*, 2008) [61,46,62,63]. Hence material from 15 RCTs is considered here (see table 7).

In comparison with open colposuspension the objective cure rate from sling operations was not significantly

different within the first year (RR 0.19; 95% CI 0.02 to 1.53) or on longer follow-up (RR 0.49; 95%CI 0.17 to 1.42) [EL=1]. Other outcomes were not analysable in the Cochrane review. The most recent, and by far the largest and most rigorous RCT of colposuspension and fascial sling randomised 655 women of whom 520 were assessed at 24 months; this was not included in the Cochrane review. This showed significantly better combined subjective and objective outcome in terms of any incontinence 38% vs. 47% ( $p=0.01$ ) and SUI 49% vs. 66% ( $p<0.001$ ) from the sling procedure; adverse events in general (47% vs.63% ( $p<0.001$ )) and voiding difficulty in particular (14% vs. 2%,  $p<0.001$ ) were more common in sling group (Albo *et al.*, 2007) [46] [EL=1].

Only one small trial is available to allow comparison between sling (porcine dermis) and needle suspension (Stamey) in a group of women unsuitable for abdominal colposuspension because of vaginal narrowing secondary to either previous interventions or atrophic change (Hilton, 1989) [96]. Although there were no differences in objective cure rates at 3 or 24 months, peri-operative complications (RR 4.50; 95% CI 1.28, 15.81) and length of hospital stay (RR 13.00; 95% CI 5.00, 21.00) favoured the needle suspension procedure [EL=2].

In the Cochrane review, trials comparing rectus fascia with other materials heavily weighted the comparison different types of sling (Bezerra *et al.*, 2005) [16]. Failure rates were similar both in the short (RR 0.96; 95% CI 0.59, 1.55) and long-term (RR 0.69; 95% CI 0.41, 1.16).

## 1. SYNTHETIC SLINGS

A *silicone sling material reinforced with woven polyethylene terephthalate (Dacron®)* was described by Stanton and colleagues (Stanton *et al.*, 1985a) [26]. No high level evidence relating to procedures utilising this material was identified; three case series reported outcomes in 124 women (Stanton *et al.*, 1985a, Korda *et al.*, 1989, Duckett & Constantine, 2000) [26,168,169]. The subjective cure rate was 79% at mean follow-up of 15 months in one series, and both subjective and objective cure rates were 83% at 3 months in another. Intra-operative complications were common, including haemorrhage requiring blood transfusion (6%) and vaginal, bladder or urethral perforation (7% each). The need for sling adjustment or removal because of sinus or fistula formation was found in all series, and sling removal was required in 5 out of 7 patients (71%) in one series (Duckett & Constantine, 2000) [169] [EL=3].

Three small controlled trials evaluated a *polytetrafluoroethylene (PTFE – Gore-Tex®)* sling in comparison to open colposuspension (Sand *et al.*, 2000, Culligan *et al.*, 2003) [57,59], rectus fascial sling (Barbalias *et al.*, 1997) [159], and vaginal wall

**Table 7. Published level 1 & 2 evidence relating to traditional sling procedures for the treatment of stress urinary incontinence Notes: patient numbers are given as – total no. followed up or analysed /total no. recruited (no. in index group: no. in comparator group) SS = sample size; ITT = intention to treat**

Study references	Type	Comparator	MIN (n1:n2)	FU	Cure (obj or subj)/ effect size	EL	Comments
1 (Henriksson & Ulmsten, 1978) [84]	Quasi-RCT	Sling (Zoedler, vaginal) vs. MMK	30/30 (15:15)	3m	100% vs. 100% (o)	2	Quasi-RCT - by alternation. No ss calculation; analysis not clear if ITT.
2 (Hilton, 1989) [96]	RCT	Sling (porcine dermis) vs. Stamey needle suspension	20/20 (10:10)	2y	90% vs. 80% (o - at 3m) 90% vs. 70% (s - at 2y)	2	Included only USI with vaginal narrowing unsuitable for colpo.
3 (Enzelsberger et al., 1996) [56]	RCT	Sling (dura mater) vs. Colposuspension	72/72 (36:36)	32-48m	92% vs. 86%	2	No ss calculation; analysis not clear if ITT.
4 (Barbaliás et al., 1997) [159]	RCT	Sling (Goretex) vs. Sling (rectus fascia)	48/48 (16:32)	6m & 30m	88% vs. 81% (s - at 6m) 88% vs. 65% (s - at 12m)	2	No baseline data reported per treatment group, no analysis of results.
5 (Lucas et al., 2000) [160] (Guerrero et al., 2007) [167]	RCT	Sling (rectus fascia) – standard (20cm long) vs. Sling-on-a-string (8–10cm long)	165/168 (81:84)	12m & 25-60m (mean 42m)	84 vs. 84%; p=ns (s - at 12m) 40%-53% vs. 36%-51% on sensitivity analysis; p=ns (s at mean 42m)	1	
6 (Sand et al., 2000) [57] (Culligan et al., 2003) [59]	RCT	Sling (Gore-tex) vs colposuspension	28,36/37 (17:19)	3m/33-116m	100% vs. 90%; p=ns (o - 3m) 100% vs. 85%; p=ns (o - longer-term)	2	Only 28 in longer-term FU; concurrent procedures in 21% vs. 12%
7 (Choe et al., 2000) [170]	Quasi-RCT	Sling (PTFE - MycroMesh) vs. Sling (vaginal wall)	40/40 (20:20)	12-27m	95% vs 75% (s+o - at mean 22m)	2	
8 (Demirci & Yucel, 2001) [58]	Quasi-RCT	Sling (rectus fascia) vs. colposuspension	34/46 (17:17)	1y	94% vs. 88%; RR 2.00; 95% CI 0.20, 20.04 (o)	2	Quasi-RCT - by alternation. No ss calculation; analysis not clear if ITT.

**Table 7. Published level 1 & 2 evidence relating to traditional sling procedures for the treatment of stress urinary incontinence Notes: patient numbers are given as – total no. followed up or analysed /total no. recruited (no. in index group: no. in comparator group) (Continued)**  
**SS = sample size; ITT = intention to treat**

	Study references	Type	Comparator	N/N (n1:n2)	FU	Cure (obj or subj)/ effect size	EL	Comments
9	(Viseshsindh <i>et al.</i> , 2003) [164]	RCT	Sling (rectus fascia) vs. Sling (vaginal wall)	26/26 (15:11)	3-12m	93% vs. 100%; p=ns	2	lack of details re randomisation, analysis of results.
10	(Arunkalaivanan & Barrington, 2003) [162] (Abdel-Fattah <i>et al.</i> , 2004) [179]	RCT	Sling (porcine dermal collagen – Pelvicol) vs. TVT	128/142 (74:68)	6-24m & median 36m	85% vs. 89% (s – at median 12m) 88% vs. 82% (s – at median 36m)	2	
11	(Lucas <i>et al.</i> , 2004) [165]	RCT	Sling (rectus fascia sling-on-a-string (8–10cm long) vs. TVT Sling (porcine dermal collagen – Permacol)	70, 97/139 (33:31:40)	12m	88% vs. 80% vs. 76% (s – 6m) 81% vs. 83% vs. 53% (s – at 12m)	2	260 required from SSC; 139 recruited; FU data available from 97 at 6 months & 70 at 12 months. Permacol arm of trial stopped early because of results of interim analysis.
12	(Maher <i>et al.</i> , 2005) [141]	RCT	Sling (rectus fascia) vs. Silicone particles (Macroplastique)	45/45 (22:23)	6m	81% vs. 9%; p<0.0001	2	Silicone injected transurethrally.
13	(Bai <i>et al.</i> , 2005) [60]	RCT	TVT Colposuspension	92/92 (28:31:33)	1y	93% vs. 87% vs. 88%; p<0.05 for sling vs. others	2	Disparities between text and tables. No ss calculation.
14	(Wadie <i>et al.</i> , 2005) [166]	RCT	Sling (rectus fascia) vs. TVT	53/53 (25:28)	6m	92% vs. 92%; p=ns (o – at 1 week)	2	No SS calculation; appears underpowered; cure determined at first FU visit.
15	(Tennstedt & Urinary Incontinence Treatment Network, 2005) [61] (Albo <i>et al.</i> , 2007) [46] (Richter <i>et al.</i> , 2008) [63]	RCT	Sling (rectus fascia) vs. Colposuspension	520/655 (326:329)	2y	66% vs. 49% (p<0.001) (s+o)	1	50% concomitant surgery for POP; 79% outcome assessment at 2 years.



sling (Choe *et al.*, 2000) [170] (total n = 124). In a RCT against open colposuspension, although the groups were different at baseline in terms of the proportion with detrusor overactivity (DO), cure rates with PTFE were not significantly different from open colposuspension at 2.5 years (objective 100% vs. 85%; subjective 84% vs. 93%) (n = 36) (Sand *et al.*, 2000, Culligan *et al.*, 2003) [57,59] [EL=2]. In a RCT against fascial sling the combined objective and subjective cure rates were 88% and 81%, respectively, at 6 months (Barbalias *et al.*, 1997) [159]. A quasi-randomised comparison with vaginal wall sling gave no statistical analysis, but found combined subjective and objective cure in 95% vs. 75% at mean follow-up of 22 months (Choe *et al.*, 2000) [170] [EL=2]. Again, the need for sling removal is common, reported in up to 31% (median 8%) in a review of case series within the systematic review underlying the NICE guidance on UI (National Collaborating Centre for Women's & Children's Health, 2006, National Institute for Health & Clinical Excellence, 2006b) [EL=3].

Only low level evidence is available to evaluate slings made of *polyester* (Mersilene®). Four case series evaluated a Mersilene® sling with follow-up from a mean of 2 years to 5 years (Kersey, 1983, Kersey *et al.*, 1988, Guner *et al.*, 1994, Young *et al.*, 2001) [171-174]. Subjective cure rates across the studies ranged from 50% to 96% (median 84%). The objective cure rate in 52 women followed-up at 5 years in one study was 94%, compared to 95% at 1 year (although this only represented a quarter of the women treated) (Young *et al.*, 2001) [174] [EL=3].

## 2. BIOLOGICAL SLINGS

Nearly all RCTs of biological slings compare the autologous rectus fascial sling procedure with a range of other surgical interventions. RCTs evaluating dura mater and porcine dermal slings were also identified.

### i) Rectus fascial sling

One RCT compared autologous rectus fascial sling with periurethral silicone injection in women with stress UI secondary to LSD in whom conservative treatment had failed. At 6 months, no significant differences were seen between groups in subjective cure or satisfaction, QOL (UDI-6, IIQ). Significantly more women undergoing sling surgery were objectively cured on the basis of urodynamic assessment (81% vs. 9%;  $p=0.0001$ ), but duration of the procedure, catheterisation, inpatient stay, and time to return to normal activities were significantly longer. A survey of two-thirds of the women at 5 years found no statistically significant differences between groups in urinary symptoms or in satisfaction with surgery (n = 45).557 [EL=2]

Open continence surgery (a suspension procedure in 46% and fascial sling in 54%) was compared with periurethral collagen in women with stress or mixed

UI in a further RCT. Again there were no significant differences in patient satisfaction or QOL (SF-36, IIQ) between groups at 1 year. Using intention-to-treat analysis there was no significant difference in continence rates at 1 year (52% collagen, 55% surgery); if only the 89% of women who underwent the randomised intervention were considered, the continence rate with surgery was significantly higher (72% vs. 53%;  $p=0.01$ ). The incidence of adverse effects was significantly higher in the surgery group: urinary retention 13% versus 2%, transient voiding difficulty 36% versus 17%, UTI 6% versus 0% (n = 133) (Corcos *et al.*, 2005) [140] [EL=2].

Three RCTs have compared autologous rectus fascial sling with TVT involving a total of 284 patients (Bai *et al.*, 2002, Lucas *et al.*, 2004, Wadie *et al.*, 2005) [175,165,166]. Cure rates at 12 months (symptom-free +/- negative stress test in the different studies) were 83%, 87%, and 88% following TVT and 81%, 82% and 93% following rectus fascial sling; one of these trials also had a colposuspension arm, which had a 12 month cure rate of 88% (Bai *et al.*, 2002) [175], and one a porcine dermis sling arm with a cure rate of only 53% (Lucas *et al.*, 2004) [165] [EL=1/2]. One quasi RCT compared autologous rectus fascial sling with a self-fashioned polypropylene sling in 50 women, with similar findings (Kuo, 2001) [176] [EL=2]

One RCT compared rectus fascial and PTFE slings in women with stress UI, 92% of whom had had prior continence surgery. Combined objective and subjective cure rates were 81% and 88%, respectively, at 6 months. No complications were reported in the fascial sling group, whereas urethral erosion, recurrent UTI and de novo DO were very common with PTFE (n = 48) (Barbalias *et al.*, 1997) [159] [EL = 1].

Rectus fascial and vaginal wall slings were compared in one RCT and two non-randomised retrospective studies (Kaplan *et al.*, 1996, Viseshsindh *et al.*, 2003, Rodrigues *et al.*, 2004) [177,164,178]. All were considered to be of poor quality. The RCT reported high subjective cure, and satisfaction rates (80–100%), with median follow-up of 7 months (n = 26). (Viseshsindh *et al.*, 2003) [164] [EL=2]. The non-randomised studies reported similar 'success' rates with both interventions, ranging from 80% to 97%, with follow-up of 21 months, and 70 months versus 45 months (n = 232, n = 79) [EL=2].

One RCT compared two techniques of fascial sling in 168 women with urodynamic stress UI 89% of whom had had prior continence surgery. Women underwent a standard fascial sling procedure or a 'sling on a string' (a shorter sling mounted on each end with a nylon thread). At 1 year, subjective cure rates were 84% using both techniques. Satisfaction and changes in IIQ scores were also similar in both groups, whereas improvements in UDI scores were greater with the standard approach (adjusted for differences in baseline

UDI data) (Lucas *et al.*, 2000) [160]. A further follow-up of women in this study was recently reported at 5 to 7 years (Guerrero *et al.*, 2007) [167]. There were no significant differences in symptoms of SUI or UUI between groups, with 40%-53% vs. 36%-51% reporting SUI in sensitivity analysis [EL=1].

Case series of autologous rectus fascial sling were reviewed within the systematic review underlying the NICE guidance on urinary incontinence (National Collaborating Centre for Women's & Children's Health, 2006, National Institute for Health & Clinical Excellence, 2006b). Ten series including a total of 1280 women were considered. Studies had a mean or median duration of follow-up between 2 and 6 years; in three studies, maximum follow-up of 15–18 years was reported. Subjective cure rates ranged from 26% to 97% (median 81%); and cure that included subjective and objective elements 73% to 95%. Satisfaction rates of 86% and 92% were reported in two studies.

#### **ii) Dura mater sling**

One RCT compared dura mater sling with open colposuspension in 72 women with SUI after hysterectomy. The combined objective and subjective cure rates were 92% versus 86%, at about 3 years. Significantly more women in the sling group had voiding difficulty or retention postoperatively, both of which were common, and more women developed rectocele in the colposuspension group. Bladder perforation and de novo urgency were common in both groups. Time to spontaneous voiding was significantly longer in the sling group (n = 72) (Enzelsberger *et al.*, 1996) [56] [EL=1].

#### **iii) Porcine dermis sling**

One small RCT compared a porcine dermis sub urethral sling with the Stamey needle suspension procedure in 20 women with stress UI who were considered unsuitable for colposuspension. At 2 years, subjective cure rates were 90% versus 70%. Intraoperative blood loss and postoperative infection were significantly more common in the sling group. Other common complications in both groups were bladder injury and de novo DO (n = 20) (Hilton, 1989) [96] [EL=2].

One RCT comparing porcine dermis sling (Permacol®) with TVT™ found no significant differences operating time, hospital stay, complication rates, or subjective cure at 1 year (85% vs. 89%) (Arunkalaivanan & Barrington, 2003) [162] nor in cure (88% vs. 82%) or satisfaction at 3 years, assessed by mailed questionnaire (77% vs. 80%) (Abdel-Fattah *et al.*, 2004) [179] [EL=1]. One can only speculate why this study found comparable results between Permacol® and TVT™, whereas the 3-arm trial cited above found such significantly poorer results from Permacol® to require the premature curtailment of recruitment (Lucas *et al.*, 2004) [165].

#### **iv) Autograft vs. allograft vs. xenograft**

Seven non-randomised studies compared the outcomes of autologous and allograft slings in a total of 786 women with SUI; one also compared both interventions with a xenograft material (porcine dermis). All were retrospective reviews, each with differences in duration of follow-up for the interventions evaluated (between 3 months and 3 years), with drop-out rates of 4% to 34%; between 16% and 82% in different studies underwent other concomitant surgeries; all were considered to be of poor quality (Wright *et al.*, 1998, Brown & Govier, 2000, Soergel *et al.*, 2001, Flynn & Yap, 2002, O'Reilly & Govier, 2002, Almeida *et al.*, 2004, McBride *et al.*, 2005, Simsiman *et al.*, 2005) [180-187] [EL=2].

Four of these studies compared autologous with allograft (cadaveric) fascia lata. Three of these studies reported similar results for all outcomes (subjective cure, satisfaction, and UDI-6, IIQ-7 and SEAPI scores) (Wright *et al.*, 1998, Brown & Govier, 2000, McBride *et al.*, 2005) [180,181,186]; the fourth study reported significantly higher cure rates in the autologous group (Almeida *et al.*, 2004) [185] [EL=2].

In three studies that compared autologous rectus fascia or fascia lata with allograft fascia lata, two found a significantly higher cure rate in the autologous group (Soergel *et al.*, 2001, Simsiman *et al.*, 2005) [182,187]; the other found no significant differences in cure rate, although satisfaction rates were higher in the autologous group after 2 years follow-up (Flynn & Yap, 2002) [183]. In the study with a xenograft arm, cure rates were significantly higher with autograft material (Simsiman *et al.*, 2005) [187] [EL=2].

#### **Summary:**

The conclusion of the Cochrane review was that data on sub-urethral sling operations remain too few to adequately address the effects of this type of surgical treatment. They highlight the fact that many studies fail to address appropriate outcome measures to address the broader effects of the surgery, such as general health status and health economics. They also emphasise that reliable evidence on which to judge whether or not sub-urethral slings are better or worse than other surgical or conservative management is currently not available.

Autologous rectus fascial sling is the most widely evaluated biological sling, which is an effective treatment for SUI and has longevity [EL=1]. Limited data suggest that pubovaginal sling using porcine dermis is also effective [EL=1], although data relating to other biological slings are few, and generally of poor quality. There is limited evidence that rectus fascial sling may be as effective as or more effective than open colposuspension, although adverse events and voiding difficulty in particular may be more common [EL=1]. There is no high level evidence of a

difference in efficacy between biological and synthetic sling materials, although adverse events may be more common following the use of synthetic materials for 'traditional' sling procedures [EL=3]. There is no high level evidence of a difference in efficacy between different biological sling materials, although those studies that find a difference all favour autologous materials [EL=2]

### **Recommendations:**

**Autologous fascial sling is recommended as an effective treatment for stress urinary incontinence, which has longevity. [Grade A]**

**Further high quality research is required to clarify the place of 'traditional' sling procedures in relation to other procedures, and to establish the optimum sling materials. [Grade D]**

## **2. MID-URETHRAL TAPES**

The Tension-free Vaginal Tape (TVT) procedure for treatment of female urinary stress incontinence was first introduced by Ulmsten et al. in 1996. The development of the TVT operation was an attempt to support the middle portion of the urethra instead of restoring anatomy and correct urethral hypermobility at the bladder neck.

The idea of supporting the "mid-urethra" derived from discoveries of several research projects conducted during the last thirty years. Zaccharin already in 1968 [581] and DeLancey in 1994 [582] showed that the pubourethral ligaments inserted at the mid-urethra and that the urogenital diaphragm also was more close to the middle portion of the urethra than the bladder neck.

Owman et al. 1978 found that the most densely innervated portion of the urethra was the middle part and Huisman in 1983 [583] in histological studies showed that the mid-urethra had the most abundant vascularisation.

When Westby et al. 1982 [584] in radiographic studies showed how the urine stream was interrupted at the mid-urethra on holding in continent women and Asmussen et al. 1983 [585] showed that the maximal urethral closure pressure was situated at the mid-urethra it became apparent that focus on the mid urethra might bring improvement in the performance of incontinence surgery.

Prospective observational cohort studies revealed that placing a macroporous, monofilament polypropylene tape at the mid urethra resulted in cure rates between 80-90 % in primary cases of stress incontinence (Ulmsten et al 1996, Ulmsten et al 1998, Nilsson 1998, Ulmsten et al 1999, Nilsson et al 2001) [188-192], in recurrent cases (Rezapour and Ulmsten 2001, Kuuva and Nilsson 2003) [193, 194], in mixed

incontinence cases (Rezapour and Ulmsten 2001) [607] and in an unselected group of women including primary, recurrent and mixed incontinence as well as women with intrinsic sphincter deficiency (Nilsson and Kuuva 2001) [195]

### **a) RCT:s comparing TVT with traditional incontinence operations (Figure 6)**

Only around 12 randomized clinical trials comparing TVT with traditional incontinence procedures have been published in peer reviewed journals. Five of these compare TVT with open colosuspension (Ward et al. 2002, Liapis et al. 2002, Wang et al 2003, Bai et al. 2005, El-Barky et al. 2005) [65,64,66,60,68], four compare TVT with laparoscopic colposuspension (Persson et al. 2000, Ustun et al. 2003, Paraiso et al 2004, Valpas et al. 2004) [119,120,122,123], two compare TVT with a fascial sling (Bai et al. 2005, Wadie et al. 2005) [60,166] and one compares TVT with no treatment (Campeau et al. 2007) [196]. These articles are listed in Table 1. A limitation to the conclusions that can be drawn from the results obtained in these studies is the fact that most of the trials include only 23 -50 patients in each arm with no mention of power calculations. The trials by Ward et al. 2002, 2004, 2008 [65,67,64] and Valpas et al. 2004 [123] enrolled a greater number of patients and included power calculations, but neither reached the required number of patients.



**Figure 6 : The tension free vaginal tape (TVT)**



### **b) TVT vs Colposuspension**

Four of the studies comparing TVT with open colposuspension used objective outcome measures for defining cure: 1 hour pad test (Ward et al. 2002, 2004, 2008, Liapis et al. 2002, Wang et al. 2003) [65,67,45,64,66], cystometry (Ward et al. 2002) [65] and a stress test (Ward et al. 2002, 2004, Bai et al. 2005) [65,67,60]. The study by El-Barky et al 2005 [68] only used subjective outcome measures. None of these studies found any statistical differences in objective cure rates between the two operations. The cure rate varied between 63 and 87 % in the TVT groups and between 51 and 90 % in the open colposuspension groups. The time period of follow-up was between 3 and 24 months in all five trials except the 5 years extension of the Ward et al. 2008 study. This five years report is, however, hampered by a 58 % lost to follow-up in the TVT group and a 67 % lost to follow-up in the colposuspension group. Subjective cure was mostly poorly defined and validated quality of life questionnaires was only used in the Ward et al. 2002 [65] study finding no difference in subjective cure between the TVT and the colposuspension groups.

Operation time, hospital stay and time for resuming normal activity was significantly shorter in the TVT groups (Ward et al. 2002, Liapis et al. 2002, El Barky et al. 2005) [65,64,68]. The percentage of intra-operative bladder perforations was significantly greater in the TVT group than in the colposuspension group, 9 % and 3 % respectively, in the Ward et al. 2002 study while El Barky et al. 2005 reported no perforations in the colposuspension group and two in the TVT group ( $< 0.05$ ). Wound infections were more common in the colposuspension group ( $< 0.05$ ).

Significantly more patients experienced delayed voiding in the colposuspension group in the Ward et al. 2002 [65] study and in the 2 years follow-up report of the same study there were significantly more patients in the colposuspension group needing intermittent self catheterization ( $< 0.0045$ ) and surgery for pelvic organ prolapse ( $< 0.0042$ ) than in the TVT group.

### **c) TVT vs Fascial sling**

The study by Bai et al. 2005 [60] actually compared TVT with both open colposuspension and a fascial sling and found that at 3 and 6 months follow up there was no difference in cure rate between the operations, but at 12 months the fascial sling operation had a significantly higher cure rate of 92.8% than the colposuspension and TVT operations, 87.8% and 87.0% respectively. No difference in cure rates was found between the TVT and the fascial sling operations in the study by Wadie et al. 2005 [166]. In an interesting study by Campeau et al. 2007 [196] elderly women over the age of 70 years were randomized either to

immediately receive TVT surgery or had to wait for 6 months for surgery. Follow-up at 6 months by different quality of life questionnaires revealed highly significantly ( $< 0.0001$ ) higher quality of life in the operated women, even though 22.6% experienced bladder perforation and 12.9% urinary retention as a result of the surgery.

### **d) TVT vs laparoscopic colposuspension**

Laparoscopically performed colposuspension has been compared with the TVT operation in four randomized trials (Persson et al. 2000, Ustun et al. 2003, Paraiso et al. 2004, Valpas et al. 2004) [119,120,122,123] and with modified mid-urethra tape procedures as the transobturator route of tape placement (TOT) and tape placement retropublically by an abdominal approach (SPARC) in two trials: TOT by Sivaslioglu et al. 2007 and SPARC by Foote et al. 2006<sup>197</sup>.

In the studies comparing TVT, TOT or SPARC with laparoscopic colposuspension objective cure was assessed by a pad test in 2 of the six studies (Persson et al. 2000, Valpas et al. 2004) [119,123], by a stress test in four of the studies (Ustun et al. 2003, Paraiso et al. 2004, Valpas et al. 2004, Sivaslioglu et al. 2007) [120,122,123,47] while the criteria for cure or improvement was rather unclear in the study by Foote et al. 2006 [197]. The trial by Valpas et al. 2004 [123] with the greatest number of patients enrolled showed a significantly higher objective and subjective cure rate in the TVT group than in the laparoscopic colposuspension group ( $< 0.0001$ ), while the other studies showed similar cure rates for both procedures ranging between 72.9% and 96.8% in the TVT groups and between 58.8% and 87% in the laparoscopic colposuspension groups.

Although laparoscopically performed colposuspension is regarded as a less invasive operation than the open colposuspension the mid-urethra tape procedures had significantly shorter operating time ( $< 0.001$ ), hospital stay ( $< 0.001$ ) and time for resuming normal activity ( $< 0.01$  - $0.001$ ) than the laparoscopic colposuspension.

### **e) Metaanalyses of TVT vs other procedures**

Novara et al. 2007 [586] published a meta-analysis of randomized controlled trials comparing Tension-free mid-urethral slings with other surgical procedures for treatment of stress incontinence. They concluded by meta-analysis that the TVT procedure outperformed the Burch colposuspension and that the efficacy of the TVT was similar to pubo-vaginal slings. A review by Dean et al. 2006 [18] including seven randomized trials comparing laparoscopic colposuspension with TVT found an overall objective cure rate within 18 months of follow-up to be significantly higher in the TVT group.

**f) RCTs comparing TVT with modifications of the retropubic tape placement**

The favorable results obtained with the TVT operation have resulted in several modifications of the procedure and the use of different tape materials. These retropubic modifications have been poorly clinically evaluated and only seven randomized studies comparing these with the TVT have been published. Three trials compare the TVT with the Supra Pubic Arc Slings (SPARC) which utilizes a polypropylene tape material, but differs from the TVT by approaching the mid-urethra from an abdominal incision (Tseng et al. 2004, Adonian et al. 2005, Lord et al. 2006). [198,199,200] The study by Lord et al. including 147 TVT and 160 SPARC cases showed a significantly higher subjective cure rate in the TVT group. They also found that the SPARC procedure was significantly more often associated with tape erosion and was more difficult to adjust with the need of tape loosening in the operating theater than the TVT procedure (<0.002). Tseng et al.[198] reported a 12.9 % of bladder perforation in the SPARC group with none in the TVT group. The difference was not statistically significant in this small study with only 31 patients in each group, but the authors stated it to be clinically significant.

One study compares TVT with an allogenic graft material made from acellular porcine collagen, the Pelvicol. Arunkalaivanan et al.[162] report on the results in two articles, the 12 months results in 2002 and the 36 months results in 2004. Outcome was assessed in both reports by a postal questionnaire and found no difference in subjective cure rate between the groups of 68 TVT operations and 74 Pelvicol operations.

Three trials compare TVT with the Intra Vaginal Slings (IVS) procedure, which utilizes a multifilament, miniporous polypropylene tape material (Rechberger et al. 2003, Lim et al. 2005, Meschia et al. 2006) [201-203]. In the study by Meschia et al. including 95 patients in each group the objective cure rate was 85% for the TVT and 72% for the IVS and the subjective cure rate was 87% and 78% respectively, with no difference between groups. There was a 9% erosion rate during the 2 years of follow-up in the IVS group, with none in the TVT group. Rechberger et al found no difference between the groups in their 13 months follow-up of 50 patients per group. Lim et al. [77] compared TVT with both IVS and SPARC, with 65 patients in each group. The subjective cure rates between 6 and 12 months of follow-up were 87.9% in the TVT group, 81.5% in the IVS group and 72.4% in the SPARC group, the differences not being significant. They found a significantly greater rate of tape protrusion in the SPARC group compared to both TVT and IVS (<0.04). Most concerning is the report by Balakrishnan et al. 2007 [587] in which they followed the subgroup of IVS patients of the Lim et al [202]. study for up to 30 months and found that 13%

had sling erosions requiring sling removal and that of the 29 patients (47%) of the initial IVS group who were seen 12 to 34 months post-operatively 24% experienced sling erosion with sinus formation and requiring sling removal.

The meta-analysis by Novara et al. 2007 [586] concludes that the TVT is more effective than both the IVS and the Sparc.

**g) RCT:s comparing TVT with transobturator tape placement (Figure 7)**

The retropubic placement of the mid-urethra tapes has been associated with the risk of bladder injury, the rates varying between 0.8% and 21 % in different reports (Wang 2004, Adonian et al. 2005) [204,199]. Two systematic registries on the rates of complications associated with the TVT operation have been published, one from Finland including the first 1455 operations performed nation-wide and one from Austria including 2795 operations (Kuuva and Nilsson 2002, Tamussino et al. 2001) [205,206].

The rates of bladder perforation were 3.8% and 2.7% respectively. To avoid bladder injuries Delorme in 2001 [588] introduced a modified tape procedure in which the tape was brought to support the mid-urethra from inside the thighs through the obturator foramina on both sides, the so called outside-in transobturator tape procedure (TOT). De Leval in 2003 [589] further modified the procedure to be an inside-out procedure called the Tension-free Vaginal Tape-Obturator (TVT-O).

The original retropubic TVT has been compared with the inside-out TVT-O in six randomized trials (Zullo et al. 2007, Meschia et al.2006, Liapis et al. 2006, et al. Laurikainen et al 2007, Araco et al. 2008, Rinne et al. 2008) [207,203,208,209,210], and with the outside-in TOT in two trials (Adonian et al. 2007, Porena et al. 2007) [212,213] Wang et al. 2006 [590] compared the TOT with SPARC and found no difference in cure rate or rates of complications between the group of 31 TOT patients and 29 SPARC patients.



**Figure 7 : The transobturator tape**



Five of the studies comparing TVT with TVT-O included power calculations either for detection of differences in cure rates and complication rates (Meschia et al. 2006, Laurikainen et al. 2007, Rinne et al. 2008) [203,209,211], or only for detection of differences in complications (Zullo et al. 2007) [207]. The study by Liapis et al [208] reported no power calculations. No differences in the overall objective or subjective cure rates were seen between the TVT and the TVT-O procedures during follow-up periods of 6 to 12 months. The only statistically significant difference in objective cure rate was seen in the Araco et al. [210] report where a stratification between mild and severe stress incontinence had been made. They found a significantly higher cure rate in the TVT patients with severe stress incontinence than in the TVT-O patients with the same condition: 100% versus 66 % cure respectively (<0.001).

Somewhat contradictory results concerning complications arise from the trials. The reports by Meschia et al.[203] and Laurikainen et al., [209] including 3-4 times more patients than the reports by Zullo et al. [207] and Liapis et al. [208] show either no differences in the overall number of complications or a significantly higher rate of overall complications in the TVT-O group (Laurikainen et al.) It is not clear from the Zullo et al. study, which showed a higher complication rate for the TVT, how the overall complication rate was calculated.

The two trials comparing TVT with TOT (Porena et al. 2007, Andonian et al.2007) [213,212] found no difference in cure rates between the procedures. There were no differences in complication rates between the procedures in the Porena et al. report, while Andonian et al. reported significantly greater rates of complications in the TOT than in the TVT group.

Two trials have compared the inside-out procedure (TVT-O) with the outside-in procedure (TOT). But and Faganelj 2007 [591] included 60 patients in each group and found no difference in subjective cure rate between the procedures at 4 months follow-up, 90.7% for the TVT-O and 88.7% for the TOT respectively. Lee et al. 2008 [592] concludes that in their underpowered study no differences in objective or subjective cure rate was seen and no differences in complication rates.

#### **h) *Metanalyses***

The meta-analysis by Novara et al 2007 [586] found overlapping cure rates with the retropubic and transobturator procedures. A meta-analysis by Latthe et al. 2007 [593] also arrived at equal cure rates for both the retropubic and transobturator route of mid-urethra tape placement the follow-up period though being only 2-12 months. There seems to be no difference in complications between the TVT procedure and the transobturator procedures.

## **CONCLUSION**

There is evidence that the retropubic TVT is more effective than the Burch colposuspension and equally effective as traditional fascial sling operations (Level 1/2).

Operation time, hospital stay and time to resume normal daily activity is shorter with the TVT than with colposuspension. Post-operative voiding problems and need for urogenital prolapse surgery are more commonly associated with colposuspension, while bladder perforation is more commonly associated with TVT (Level 1/2).

TVT is more effective than the IVS and the SPARC procedure (Level 1/2).

Retropubic and transobturator placement of monofilament tapes at the mid-urethra perform equally at a short term follow-up of 6 to 12 months and overall complication rates are comparable (Level 1/2) (**Table 7 a**).

## **II. CONFOUNDING VARIABLES**

### **1. AGE**

Although there is extensive historical reporting of efficacy and low morbidity associated with various sling technologies, the affect of age on outcomes is relatively undefined. The affect of aging on the lower urinary tract includes a higher rate of detrusor overactivity, as well as, urge incontinence and intrinsic sphincteric deficiency. In addition, older patients are more likely to have had prior interventions, and may, therefore, may have a higher rate of peri-urethral fibrosis and/or other abnormalities in the area tissues surrounding the lower urinary tract. The presence of multiple co-morbidities may also affect overall surgical outcome, including creating the possibility for increased complication and prolonged post-operative course. Variable rates of success have been reported by numerous authors [214,215,216].

When evaluating mid-urethral slings in older women, the definition of age is controversial. The most extensive study of older patients is that of Gordon [217], who evaluated 460 consecutive women undergoing transvaginal tape (TVT). By characterization of age (greater than 70 years), 157 (34%) were considered to be elderly. These patients underwent pre-operative and three-month post-operative urodynamic outcomes, as well as symptom appraisal. All patients were followed for at least twelve months, with a mean follow-up of 26 months. In the older age population, there was a greater prevalence of mixed incontinence (31%), when compared to the younger patients (23%). In addition, concomitant pelvic organ prolapse surgery was undertaken in a greater percentage of the older patients (84%), when

**Table 7a. Studies comparing TVT with modifications of retro-pubic and obturator procedures**

Reference	Years	Type of operation	No of Pts	Duration of follow-up	Power calculation	Lost to f-u %	Cure rate obj %	cure rate subj %	Significans	Level of evidence
Ward et al 2002	2002 (65)	TVT vs OC	175/169	6 mos	yes, nr	na	66/57	na	no	1
Ward et al 2004	2004 (67)	TVT vs OC	175/169	2 yrs	yes, nr	19/26	63/51	na	no	1
Ward et al 2008	2008 (45)	TVT vs OC	175/169	5yrs	yes, nr	58/67	81/90	91/90	no	2-jan
Liapis et al 2002	2002 (64)	TVT vs OC	36/35	2yrs	no	na	84/86	na	no	2
Wang et al 2003	2003 (66)	TVT vs OC	49/49	22 mos	no	na	82/76	92/93	no	2
Bai et al 2005	2005 (60)	TVT vs OC	31/33	12 mos	no	0/0	na	87/87.4	no	2
El-Barky et al 2005	2005 (68)	TVT vs OC	25/25	3-6 mos	no	0/0	na	72/72	no	2
Persson et al 2002	2002	TVT vs LBC	38/32	12 mos	yes, nr	2 and 2	89/87	57/52	no	1
Ustun et al 2003	2003 (120)	TVT vs LBC	23/23	3 mos	no	0/0	82.6/82.6	82.6/82.6	no	2
Paraiso et al 2004	2004 (122)	TVT vs LBC	36/36	12 mos	yes, nr	8 and 6	97/81	na	0.05	1 favors TVT
Valpas et al 2004	2004 (123)	TVT vs LBC	70/51	12 mos	yes, nr	6 and 4	85.7/56.9	82/58	0.001	1 favors TVT
Bai et al 2005	2005 (60)	TVT vs sling	31/28	12 mos	no	0/0	na	87/92.8	0.05	2 favors sling
Wadlie et al 2005	2005 (166)	TVT vs sling	28/25	1 week	no	0/0	93/92	na	no	2
Campeau et al 2007	2007 (196)	TVT vs no treatment	31/27	6 mos	yes, nr	0/20	na	na	0.0001	1 favors T VT
Footte et al 2006	2006 (197)	SPARC vs LBC	49/48	27 mos	yes, nr	10 and 10	na	77.4/81.4	no	2
Sivaslioglu et al 2007	2007 (47)	TOT vs SPARC	49/51	2 yrs	no	35/39	87.5/87	87.5/83.8	no	2
Adonian et al 2004	2005 (199)	TVT vs SPARC	43/41	12 mos	yes	0/0	95/83	na	no	1
Lord et al 2006	2006 (200)	TVT vs SPARC	147/154	6 weeks	yes	0/0	97.3/97.4	87.1/76.5	no	1
Arunkalavanan et al	2003 (162)	TVT vs Pelvicol	68/74	12 mos	no	0/0	na	74/76	no	2
Abdel-Fattah et al	2004 (179)	TVT vs Pelvicol	68/74	36 mos	no	12 and 8	na	88.3/82.4	no	2
Rechberger et al	2003 (201)	TVT vs IVS	50/50	4-18 mos	no	0/0	na	88/80	no	2
Lim et al 2005	2005 (202)	TVT vs IVS	65/65	6-12 weeks	no	0/0	na	82.8/83.9	no	2
Mascia et al 2006	2006 (203)	TVT vs IVS	95/95	24 mos	yes	3 and 8	85/72	87/78	no	1
Zullo et al 2006	2007 (207)	TVT vs TVT-O	35/37	12 mos	yes	0/0	91/89	na	no	2
Meschia et al 2006	2006 (203)	TVT vs TVT-O	114/117	6 mos	yes	5 and 6	92/89	92/87	no	1
Liapis et al 2006	2006 (208)	TVT vs TVT-O	46/43	12 mos	no	0/0	89/90	73.9/76.7	no	2
Laurikainen et al	2007 (209)	TVT vs TVT-O	136/131	2 mos	yes	0/0	98.5/95.4	na	no	1
Araco et al 2008	2008 (210)	TVT vs TVT-O	120/120	12 mos	yes, nr	10/16.6	100/66	na	0.001	1 favors TVT
Rinne et al 2008	2008 (211)	TVT vs TVT-O	136/131	12 mos	yes	1.5/0.8	95.5/93.1	90/93	no	1
Andonian et al 2006	2007 (212)	TVT vs TOT	80/78	12 mos	yes	0/0	86/83	na	no	1

**Table 7a. Studies comparing TVT with modifications of retro-pubic and obturator procedures**

Reference	Years	Type of operation	No of Pts	Duration of follow-up	Power calculation	Lost to f-u %	Cure rate obj %	cure rate subj %	Significans	Level of evidence
Wang et al 2005	2004 (204)	SPARC vs TOT	29/31	9 mos	yes	na	na	na	no	2
But et al 2007	2007 (591)	TVT-O vs TOT	60/60	4 mos	no	0/0	98.3/98.3	90.7/88.7	no	2
Lee et al 2008	2008 (592)	TVT-O vs TOT	50/50	12 mos	no	0/0	86/92	62/68	no	2

compared to the younger patients (67%). Intra-operatively, the rates of blood loss between older and younger patients were similar, although there were fewer bladder perforations encountered in the elderly patients. Post-operative complications such as wound infection and urinary tract infection were similar between the two groups but older patients experienced age-related problems at a greater rate, including pulmonary embolism (two); DVS thrombosis (one); pneumonia (one); and cardiac arrhythmia (two). There was no increased risk of device erosion or extrusion in the older patients. There was also no significant difference between the two groups in post-operative voiding dysfunction although one patient in the older group did require urethrolisis. Failure to cure SUI was not encountered to any greater extent in the older population and rates of post-operative urge incontinence were also similar. A higher rate of de novo urge incontinence was encountered in the older patients (18% versus 4%). Smaller studies have documented the higher rates of de novo urgency in older patients [218]

In one study the authors analyzed the potential influence of lack of urethral hypermobility (as defined as Qtip test < 30 degrees) [229]. Of those patients with no hypermobility, 71% were cured, compared with 100% with a positive Qtip test (>30 degrees). The rate of retention immediately post-operatively was 26.3%, and only one patient had persistent urinary retention of greater than one week. At a mean follow-up of 24.6 months, 67% of the patients were considered to be cured by subjective and objective means; ten (13.7%) had persistent SUI, and 14 (18.4%) had de novo urge incontinence. These results suggest that pre-operative urethral hypermobility in both younger and older women is associated with a higher cure rate.

Post-operative voiding dysfunction and especially de novo urgency, appears to occur at a greater rate in older populations, as compared to the younger populations. lallahdin estimated a post-operative urgency symptom rate of 60% in women older than 70 years, of whom 44% had de novo symptoms. Additionally, a sensation of impaired post-operative emptying was also reported by Sevestre [218].

Considering the overall impact of voiding dysfunction and other complications in overall quality of life, Walsh, using King's Health Questionnaire, noted that younger patients (defined as less than 70 years) experienced a greater improvement following stress incontinence surgery than older patients [219]. In addition, older patients had a higher rate of detrusor overactivity, pre-operatively (24% versus 9%), and also had a higher rate of prior surgery for incontinence (67% vs. 28%). They identified a similar post-operative outcome, but with a somewhat extended post-operative hospitalization, as compared to the younger population.

## 2. RACE

There are clear differences in the prevalence of SUI among racial groups (Dooley, Kenton et al. 2008) [594] (Anger, Saigal et al. 2006) [221] however whether these differences have implications in the treatment of SUI, especially the surgical treatment of SUI, is unclear. Racial disparities in the US may exist among patients undergoing surgery for SUI. In one study in US women over the age of 65, Caucasians and Hispanics were more likely to be diagnosed with SUI and undergo sling surgery for the condition as compared to non-whites (Anger, Rodriguez et al. 2007) [232]. One other study suggested that US Caucasians are 5x more likely to undergo SUI surgery than blacks (Waetjen, Subak et al. 2003) [223]. However, non-whites are approximately twice as likely to suffer complications as a result of the surgery (Waetjen, Subak et al. 2003) [223] (Anger, Rodriguez et al. 2007) [222]. Whether this is due to actual racial differences or other factors such as disparities in health care services is unclear. Race does not appear to be related to symptom severity or bother in those undergoing SUI surgery (Kraus, Markland et al. 2007) [224] and does not appear to be independently associated with quality of life outcomes (Ragins, Shan et al. 2008) [595] or surgical outcomes (Daneshgari, Moore et al. 2006) [226].

There is little data on whether a particular surgical approach is more effective or is associated with more morbidity in any given racial group as compared to another. The small amount of underpowered data available suggests that race does not independently predict for failure following SUI surgery (Richter, Diokno et al. 2008) [63].

## 3. OBESITY

There are no prospective randomized studies that have examined obesity as an independent variable across different anti-incontinence surgical procedures or within the same procedure. Obesity has been studied only retrospectively in case series as a risk factor for success or morbidity in stress incontinence surgery (Level 4 evidence).

There are no prospective, randomized trials that suggest superiority of one surgical technique over another in the obese population. Recent studies have focussed on complication rates and outcomes from mid-urethral tapes; the analysis of the influence of obesity is therefore divided into mid-urethral tapes and other surgeries.

### a). Other surgeries

Several studies have suggested increased failure rates among obese patients undergoing needle bladder neck suspensions (O'Sullivan DC et al 1995) [227], (Lo TS et al 2003) [228], (Varner RE et al 1990) [596] or retropubic suspensions (Alcalay M et al 1995)

[82], (Brieger G & Korda A 1992) [230] (Kjohlhede 2005) [231]. In contrast a retrospective study of anti-incontinence surgery in 198 women demonstrated that overall continence did not correlate with obesity in patients undergoing anterior colporrhaphy, anterior colporrhaphy with needle bladder neck suspension or Burch colposuspension although cure rates were markedly better in those in the Burch colposuspension cohort overall (Zivkovic F et al 1999) [597]. One small case series suggested that fascial slings are effective in the morbidly obese patient (Cummings JM et al 1998) [233]. In this study, 2/4 patients failed bladder neck suspension surgery whereas there were no failures in the 12 patients undergoing fascial slings.

### b). Mid-urethral tapes

#### 1. COMPLICATIONS OF SURGERY

A review of the influence of obesity on pelvic floor disorders (Jerod Greer W et al 2008) [234] identified seven studies which compared the complications of tension free vaginal tape (TVT) surgeries between 251 obese and 700 non-obese patients. Bladder injury was the only complication reported consistently enough for meta-analysis in six of the studies. The overall perforation rates were 1.2% in the obese group and 6.6% in the non-obese group ( $p=0.015$  ; OR 0.277, 95% confidence interval 0.098-0.782). Only one of the studies demonstrated a difference in TVT complications (Skriapas et al 2006) [235]. A higher risk of immediate post-operative complications was reported in morbidly obese women (BMI>40) compared to non-obese women (BMI<30) ; 48.4% in the morbidly obese compared to 38.5% in the non-obese. Complications observed in the morbidly obese but not in the non-obese included minor wound haematoma (n=2), deep vein thrombosis (n=2), pneumonia (n=1) and cardiac arrhythmia (n=1) whilst there was no differences in blood loss, operating time, hospital stay or length of time catheterised post-operatively. Jerod Greer W et al also noted that although TVT surgery on the obese patient is perceived to be more difficult by surgeons there is no evidence from a review of seven additional TVT studies that complications such as blood loss and visceral injuries is higher in obese patients. Even when a significantly longer operating time was reported this was not associated with a higher complication rate (Rogers R et al 2006) [236].

#### 2. EFFICACY

Although several studies comparing outcome from TVT in obese and non-obese women report similar efficacy Jerod Greer et al 2008 found that meta-analysis of seven studies which included 453 obese and 1,186 non-obese women revealed a significant difference in cure rates (81% vs 85%  $=<0.001$  ; OR 0.576, 95% confidence interval 0.426-0.779). Most of these studies are limited by their length of follow up (6-24 months).



Longer term follow up might be expected to reveal a progressive increase in the difference in cure rate between the obese and non-obese. Furthermore, Hellberg et al 2007 [598] reported that the failure rate appears to rise more when the BMI is >35 compared to >30.

There are no studies, prospective or retrospective, that have suggested obesity has a positive or favourable influence on outcome in stress incontinence surgery.

#### 4. PSYCHIATRIC ILLNESS

Despite the obvious association between psychological or personality factors and satisfaction with treatment, minimal research has been done on the influence of such factors on subjective or objective surgical success. Black et al found women undergoing stress incontinence surgery in the United Kingdom to be demographically similar to the general population, although mental health status was not specifically compared (Black NA et al 1996) [237]. Baseline symptom impact correlated positively with mental health, symptom severity, poorer socioeconomic status, and youth.

In a study of 45 women who underwent retropubic cystourethropexy or pubococcygeal repair, baseline lower neuroticism correlated with subjective and pad test cure at one year (Berglund A et al 1997) [34]. Higher extraversion correlated with subjective but not objective cure. Depression decreased in women objectively cured, but not those improved/failed; the decrease in depression in those subjectively cured did not reach statistical significance. Baseline somatic anxiety, psychic anxiety, and psychasthaenia (obsessive-compulsive) characteristics were higher in women subjectively failed/improved than those cured or than a reference group. The multiple comparisons and small sample size in this study make some chance associations likely. The same subjects analyzed in a different study showed the cured group to have a higher baseline degree of social integration than the improved group (Berglund A et al 1996) [31]. No differences were found in baseline or follow-up intimate relationship measures.

Öbrink et al detected above-average levels of neuroticism and depression in women who reported failure of their continence surgery without objective urine loss at 10 to 20 year follow-up (Obrink A et al 1979) [238]. Below-average levels were found in women with objective but not subjective failure. In 63 women who underwent a Burch procedure, symptomatic improvement was associated with fewer sleep disturbances and less tension (Rosenzweig BA et al 1991) [240]. Subjectively persistent incontinence was associated with more depression and sleep disturbance.

There is Level 3 evidence that psychological factors

impact on subjective and objective surgical outcomes in different ways. No data inform psychological interventions to improve the outcome of persistent incontinence or its impact.

#### 5. ACTIVITY

There is no evidence on the influence of post-operative activity on the cure rate or risk of recurrence of stress incontinence after surgery.

#### 6. PREVIOUS CONTINENCE SURGERY

As indicated in the review of procedures above, cure rates following surgery for SUI vary between 20% and 100%; for many procedures, whilst initial results may be good, long-term outcomes indicate variable recurrence rates. The mechanisms underlying initial failure and later recurrence may be quite different, although it would be counter-intuitive if prior surgery were not a significant confounding factor in the outcome of second-line treatment for SUI. The majority of studies reporting on surgery for SUI are however limited to primary cases; many others do not specify whether cases were primary or recurrent, or are inadequately powered to undertake subgroup analysis in this respect. In the review published by Jarvis less than half the reported patients were specified as primary or recurrent (Jarvis, 1994) [20]. Jarvis was however able to extract some useful data on the outcome of surgery recurrent SUI, and found that the objective results for traditional sling (mean 86.1%; 95% CI 82.4-89.8%), colposuspension (mean 82.5%; 95% CI 76.3-88.7%) and endoscopic needle suspension procedures (mean 86.4%; 95% CI 72.4-100%) were better than other procedures, with sling having the narrowest confidence intervals (Jarvis, 1994) [20].

The previous consultation suggested that women should be advised that other procedures for recurrent stress incontinence have been shown to have a lower success rate *than the same procedures used in primary SUI* (although it was also pointed out that preliminary data on the TVT procedure suggested similar cure rates in both primary and recurrent cases) (Smith, *et al.*, 2005) [23]. Amaye-Obu & Drutz undertook a retrospective review of 118/198 women treated for recurrent SUI over a 12 year period. Overall, they found similar subjective and objective cure rates for the various procedures examined, but found the cure rate following colposuspension was lower in women with more than one previous unsuccessful procedure, whereas the results following slings were maintained in women who had undergone 2 previous failed operations (colposuspension 81%, 25% and 0%, sling 77%, 73% and 38%, for 1, 2, and 3 previous unsuccessful procedures respectively) (Amaye-Obu & Drutz, 1999) [241] [EL=3]. It should be noted that the number of patents with >2 previous procedures in this series was very small.



### **a) Open colposuspension for recurrent SUI**

Case series reporting the outcome of colposuspension for the treatment of recurrent SUI after previous surgical treatment have shown variable results, with an objective cure rate at median follow-up of 9 months of 81% and 86% in two studies (Maher, *et al.*, 1999, Bidmead, *et al.*, 2001) [80,81], but 61% and 65% at 5-15 years in two studies using a Kaplan-Meier analysis (Alcalay, *et al.*, 1995, Thakar, *et al.*, 2002) [82,83] [EL=3]. The latter study in particular found no correlation between outcome and age, past hysterectomy, number of previous incontinence procedures, parity, body mass index or blood loss at operation (Thakar *et al.*, 2002) [83].

### **b) Laparoscopic colposuspension for recurrent SUI**

As noted above, one small RCT reported in abstract form only compared laparoscopic colposuspension and TVT in the treatment of recurrent SUI found similar success, complication and re-operation rates, although TVT was associated with reduced operating time, hospital stay and return to normal activity (Maher, *et al.*, 2004) [121] [EL=2].

- Traditional sling procedures for recurrent SUI

Despite the supportive conclusions of Jarvis (see above) (Jarvis, 1994) [20], and the fact that the biological slings have traditionally been seen by many as treatment of choice for recurrent SUI, the Cochrane review on traditional sling procedures reported that the data on sub urethral sling operations remain too few to address the effects of this type of surgical treatment. They felt that reliable evidence on which to judge whether sub urethral slings are better or worse than other forms of management was not currently available; in particular they made no comment on the application of sling procedures in the management of recurrent SUI (Bezerra, *et al.*, 2005) [16] [EL=1]. In the review of procedures we have identified a number of recently published RCTs examining the effect of sling procedures; none however adequately address the question of sling procedures for recurrent SUI.

Since the last consultation a number of small case series have been published describing a variety of sling procedures applied to women with recurrent SUI. Petrou & Frank reported 86% subjective cures following repeat pubovaginal sling; it should be noted however that 3/14 women suffered significant post-operative complications, and only 50% were considered objectively cured at mean follow-up of 17 months (Petrou & Frank, 2001) [242] [EL=3]. Kane & colleagues reported 92% (12/13) subjective and objective cures following a bone-anchored pubovaginal sling procedures at median 2 year follow-up (Kane, *et al.*, 1999) [243] [EL=3]. A retrospective series of 72 fascia lata slings found 90% subjective cures at minimum follow-up of 6 months (Breen, *et al.*, 1997)

[244] [EL=3]. Finally, a series of in-situ vaginal wall sling procedures was compared with a historical control group of traditional polytetrafluoroethylene sling operations in the treatment of recurrent SUI; both objective (35% vs. 88%) and subjective (61% vs. 93%) were significantly poorer in the index cases (Su, *et al.*, 1999) [245] [EL=3].

### **c) Mid-urethral tapes for recurrent SUI**

In the previous consultation very limited data were available on the use of tape procedures in the treatment of recurrent SUI. Two cohort studies reported comparable cure rates in recurrent SUI to those in primary cases at mean follow-up of 9 months (Rardin, *et al.*, 2002) [246] and 4 years respectively (Rezapour & Ulmsten, 2003) [193] [EL=3]. Since then only one RCT and a number of case reports have addressed the issue of mid-urethral tapes in the management of recurrent SUI.

One small RCT comparing laparoscopic colposuspension and TVT in the treatment of recurrent SUI found similar success, complication and re-operation rates, although TVT was associated with reduced operating time, hospital stay and return to normal activity (Maher *et al.*, 2004) [121] [EL=2]; this study is still only available in abstract form.

In a prospective series of 51 women treated with TVT for recurrent SUI, the objective cure rate was reported to be 90% and subjective cure rate 80% at a two-year follow-up (Kuuva & Nilsson, 2003) [194]. Liapis *et al.* reported a small series with 12 month follow-up; the overall cure rate was 70%, although they described greater success in those with urethral hypermobility (90%) than those with a fixed urethra (33%) (Liapis, *et al.*, 2004) [239] [EL=3].

The use of repeat TVT has been reported to be successful in patients with persistent or recurrent SUI after an initial TVT procedure (Riachi, *et al.*, 2002, Villet, *et al.*, 2002) [247,248] [EL=3]. Other small case series or reports have examined the effect of shortening the original tape, claiming comparable success rates to those reported from re-operation (Villet *et al.*, 2002, Lo & Lee, 2004, Paick, *et al.*, 2004, Nam, *et al.*, 2007) [248,249,250,251] [EL=3].

One case series described five patients with SUI persisting or recurring after transobturator tape procedures successfully managed by a retropubic tape (Moore, *et al.*, 2007) [252] [EL=3].

### **Summary**

The role of previous continence surgery as a confounding factor is poorly understood, and further high level evidence is needed in this area.

It is received wisdom that most continence procedures when used in recurrent stress incontinence will have a lower success rate than the same procedures used

in primary SUI. It has been suggested that results may be even poorer following several failed procedures. There is limited low level evidence to support this latter contention [EL=3].

Short-term follow-up suggests that the results of open (and laparoscopic colposuspension) in recurrent SUI may in fact be comparable to those in primary cases; long term results from 'survival analysis' suggest a greater fall off in cures following the application of colposuspension in recurrent SUI [EL=3].

Previous meta-analysis has suggested that the results from traditional slings are as good as or better than other procedures. In primary SUI (or series where the surgical history is not specified) slings appear to have longevity. Limited low level evidence suggests high success rates in recurrent SUI; high level evidence and long-term follow-up are not available in this patient group [EL=3].

Limited low level evidence suggests that TVT is associated with a similar success rate in recurrent SUI to that seen in primary cases [EL=2/3].

This seems to apply whether TVT is applied following a previously unsuccessful TVT, other mid-urethral tape procedures, or other forms of continence surgery [EL=3].

There are not sufficient data on tape shortening or re-tensioning to evaluate these procedures.

### **Recommendation**

**Women undergoing surgery for the treatment of recurrent SUI should be aware of the uncertain long-term outcomes. [Grade B]**

**Whilst only limited low level evidence is available currently, colposuspension, traditional biological slings and retropubic mid-urethral tape procedures are recommended in the management of recurrent SUI. [Grade B]**

## **7. HYSTERECTOMY AT THE TIME OF CONTINENCE SURGERY**

Based largely on low level evidence, the last consultation concluded that concurrent abdominal hysterectomy had no adverse effect on the rate of cure for SUI by modified Burch colposuspension (Stanton & Cardozo, 1979, Milani, *et al.*, 1985, Langer, *et al.*, 1988) [253,254,255] [EL=2/3] or MMK (Green, 1975, Milani *et al.*, 1985) [256,254] [EL=3], and similarly vaginal hysterectomy had no adverse effect on the outcome of TVT (Darai, *et al.*, 2002) [257] [EL=3]. One cohort study found that operation-related complications were significantly increased when concomitant abdominal hysterectomy is performed with Burch colposuspension (Meltomaa, *et al.*, 2001) [258] [EL=3].

We identified no new high level evidence addressing this question specifically. Two prospective cohort studies comparing the outcomes of Burch colposuspension with and without hysterectomy have since been published (Bai, *et al.*, 2004, Argirovic, *et al.*, 2006) [259,260] [EL=2]. Neither of these studies found significant differences in cure or complications.

### **Summary**

Concurrent hysterectomy has no significant adverse or beneficial effect on the outcome of treatment for SUI by open colposuspension [EL=2], MMK [EL=3], or TVT [EL=3]. The evidence regarding operation-related complications is inconsistent [EL=2].

### **Recommendation**

**Hysterectomy is not indicated specifically for the treatment of stress urinary incontinence in women. Where hysterectomy is indicated for other reasons it may be carried out concurrently with continence surgery. [Grade B]**

## **8. SEVERITY AND DURATION OF SYMPTOMS**

Severity of SUI is difficult to measure accurately. It is tied to many factors including ambient physical activity of the patient, urethral function, and voiding frequency among others. Commonly utilized objective and subjective severity measures include pad tests and/or pad counts, urethral function tests, questionnaires, voiding diaries, quality of life scores, and bother indices. In the few prospective trials that have measured outcomes using a variety of different measurements, surgical success rates vary widely depending on the parameter (Ward, Hilton *et al.* 2004; Albo, Richter *et al.* 2007) [67,46]. Each of these outcomes is associated with significant limitations as an isolated measure and furthermore these parameters only modestly correlate with each other (Albo, Wruck *et al.* 2007) [46]. When comparing outcomes across SUI procedures, baseline severity is rarely considered and may not be comparable across trials leading to confounding factors when trying to compare procedures.

Symptom duration, especially as regards SUI treatment, is rarely reported in intervention trials. The inherent problem in reporting this data is recall bias by the patient in remembering the duration of symptoms prior to intervention. Therefore, whether duration of SUI symptoms correlates with surgical success or morbidity is unclear.

## **9. DETRUSOR OVERACTIVITY AND STRESS INCONTINENCE**

The previous edition of this consultation found only level 3 evidence to support their conclusion that women who have detrusor overactivity (DO) pre-operatively are less likely to have a favourable outcome from surgery for SUI.

Much of the data on the effect of symptomatic urge urinary incontinence (UUI) on the outcome from surgery for SUI is based on women with overactive bladder syndrome (OABS), rather than on the pre-operative urodynamic finding of DO. There are no prospective randomised trials which compare the outcome of surgery in women with and without DO. Early case series of colposuspension in DO reported cures rates as low as 24-43% (Stanton, et al., 1978, Milani et al, 1985, Lose, et al., 1988) [277,254,261] [EL=3]. Colombo et al performed a retrospective cohort study and compared 44 stress incontinent women with DO with a matched group of women with stress incontinence and a stable bladder (Colombo, et al., 1996) [55]. They reported a cure rate of 95% in the stable group compared to 75% in the unstable group two years after surgery [EL=3].

Chou et al. demonstrated a comparable outcome after sling procedures performed in stress incontinent patients with or without OABS, although only 26% of in their mixed incontinence group actually had DO (Choe, et al., 2008) [267] [EL=3]. A number of studies have examined slightly different aspects of detrusor function in urodynamically mixed incontinence. In a retrospective study of 98 women treated by colposuspension, or needle suspension procedures, Pow-Sang et al demonstrated that 'high pressure' DO was associated with a poorer outcome than in patients with stable bladders or those with 'low pressure' overactivity (Pow-Sang, et al., 1986) [262] [EL=3]. A retrospective review of 36 women who underwent a sling procedure for stress incontinence and Valsalva induced DO revealed a cure rate of stress incontinence of 92% and urge incontinence of 75% (Serels, et al., 2000) [263] [EL=3]. Koonings et al. demonstrated that in women with mixed incontinence where bladder contraction is preceded by urethral relaxation, there is a more than 90% chance that bladder overactivity will disappear after successful operation for stress urinary incontinence (Koonings, et al., 1988) [264] [EL=3].

We have only identified a further four evidence level 3 studies published since the last consultation, and these are summarised as follows. In a cohort study of 340 women treated by traditional bladder neck sling or minimally invasive mid-urethral sling, Botros et al found that more patients in the mid-urethral sling group had resolution of their DO (38% vs. 15%,  $p < 0.001$ ), and fewer developed de novo overactivity than in the bladder neck sling group (29% vs. 62%,  $p = 0.002$ ) (Botros, et al., 2005) [265] [EL=3].

In a retrospective cohort study of 51 women undergoing TVT for combined urodynamic stress incontinence and DO, Duckett & Tamilselvi found resolution of overactivity in 47% and subjective cure of urge symptoms in 63% at a minimum of six months

follow-up; stress incontinence was objectively cured in 92% (Duckett & Tamilselvi, 2006) [266] [EL=3].

In a series of 192 women undergoing sub urethral sling procedures, patient satisfaction was reported by 98% of 106 with normal detrusor function pre-operatively, 82% of 50 with underactive or acontractile detrusor function, and 75% of 36 patients with pre-operative DO ( $p < 0.05$ ) (Kuo, 2007) [599] [EL=3].

Choe et al. reported a retrospective cohort of 549 women treated by TVT; 180 had OABS in addition to SUI pre-operatively; 132 of these were seen for follow-up at 3 months. Based on a 3-day frequency-volume chart and a questionnaire responses complete resolution of OABS was seen in only 24%. Perhaps surprisingly, the rate of resolution was significantly higher in those with DO preoperatively than in those with stable bladders (37% vs. 18%;  $p = 0.021$ ) (Choe, et al., 2008) [267] [EL=3].

### Summary

It has long been accepted that women who have detrusor overactivity pre-operatively are less likely to have a favourable outcome from surgery for SUI than those with pure USI [EL=3].

The rate of resolution of stress incontinence in women with mixed USI and DO is not significantly from that seen in those with pure USI [EL=3].

Rates of 'cure', or resolution of OABS or urodynamic findings ranging from 24% to 90% have been reported in women with mixed USI and DO [EL=3].

This wide range of treatment effect may be due to differences in surgical techniques or in methodology and outcome assessment [EL=4].

Although a number of women may develop new symptoms of OABS or so-called *de novo* DO following surgery for USI, such surgery should not be considered contraindicated in women with mixed symptoms of SUI and OABS or mixed urodynamic findings of USI and DO, provided that patients are fully counselled about possible outcomes [EL=4].

### Recommendations

**Surgery for USI should not be considered contraindicated in women with mixed symptoms of SUI and OABS or mixed urodynamic findings of USI and DO. [Grade B]**

**All patients undergoing surgery for stress urinary incontinence should be appropriately counselled to allow realistic expectations of outcome; this is particularly important in those with mixed symptoms or mixed urodynamic. [Grade B]**



## 10. URETHRAL OCCLUSIVE FORCES

The influence of urethral function defined by leak point pressure or maximum urethral closure pressure is difficult to define on account of the large variation in outcome measures employed. Furthermore, other variables such as urethral mobility are often not controlled. Intrinsic sphincteric deficiency (ISD) is usually defined as a leak point pressure of < 60 or maximal urethral closure pressure (MUCP) of < 20. Rezapour reported a four-year outcome follow-up for patients undergoing TVT with ISD [193]. Of the 49 patients, only eight had immobile urethras. None of the patients with immobile urethras were cured, although three were noted to be improved. Paick also reported lower cure rates in patients with low leak point pressures, given no substantial differences in urethra hypermobility [250]. Urethral hypermobility has been predictive of mid-urethral sling success by some authors ; [269]. whilst low leak point pressures have not been predictive of success by other authors [270,271]. It would appear that a low leak point pressure is less predictive of outcome on this data when compared to the presence or absence of urethral hypermobility.

## 11. SURGEON'S EXPERIENCE

Several factors independent of the patient characteristics might affect the outcome of incontinence surgery. Such are the experience of the surgeon as a surgery performing physician, experience of the surgeon in performing a given procedure, experience of the team and the hospital within which the surgery is performed. These issues have not been studied within randomized trials or in a prospective way.

In a report by Gormley et al (2002) [272] no effect of surgeon's grade of experience or teaching status of the hospital was seen when performing pubovaginal sling procedures. There are a few reports looking at the learning curve of surgeons performing the TVT operation. The overall impression is that bladder perforations and retention symptoms occur more often during the first 15 to 50 TVT operations than later on. In a nationwide report on the introduction of the TVT procedure in Finland, where the learning curve of every single surgeon was included it was found that performance improved after the first 15 operations (Kuuva and Nilsson 2002) [273] Groutz et al (2002) [274] reported a dramatic decrease in the rate of bladder perforations from 40 % in the first 10 patients to 10% in the next 10 patients and in the last 10 of a total of 30 patients operated on by a newly trained experienced urogynaecologist no further bladder perforations occurred. Leuret et al (2001) [275] reported a similar decline in the rate of bladder perforation from 22% in the first 50 patients to 8% in the next 50 patients. McLennan et al (2005) [276] analyzed the bladder perforation rate in 278 TVT operations performed by 23 residents performing a

mean number of 12 operations each and found a linear decrease in perforation rate from 34% in the first 5 patients to 26 % in the last five of 15 patients.

There is no robust literature on how many procedures need to be performed to maintain skills nor is there evidence on whether surgical skill or experience influences the cure rate rather than the complication rate although a correlation might be expected.

## III. STRESS INCONTINENCE WITH PROLAPSE

### 1. URINARY INCONTINENCE AND PROLAPSE

Women who present with urinary incontinence as their primary symptom may also have pelvic organ prolapse which may be symptomatic or asymptomatic. The decision as to whether the prolapse should be treated surgically at the same time as the incontinence is determined by the symptoms and both the prolapse produces to the patient and the influence that the prolapse surgery may have on the outcome of the surgery for the incontinence. The following clinical scenarios may present :

- a) *Stress urinary incontinence with prolapse*
- b) *Urgency incontinence with prolapse*
- c) *Prolapse with urinary incontinence (See Prolapse Chapter)*

Where the prolapse is symptomatic it will be a matter of subjective opinion whether the incontinence or the prolapse is more significant (rather than a pathological diagnosis). If the treatment selection is based on subjective assessment it follows that the outcome from treatment must be based on subjective rather than objective measures.

#### a) *Stress incontinence with prolapse*

Women who present with stress incontinence commonly have deficient support of the anterior vaginal wall. Significant prolapse is generally defined anatomically as the presenting part of the prolapse reaching to within a cm of the hymenal remnant. Symptomatic prolapse may be more or less prominent.

Milani et al (Milani 1985) [254] (Level 3) noted that the presence of vaginal prolapse preoperatively led to a lower cure rate of stress incontinence with either the Burch colposuspension or the MMK procedure; the greater the severity of the prolapse, the greater the reduction in cure rate. In a RCT Colombo et al (Colombo 2000) [37] compared Burch colposuspension with anterior colporrhaphy in women with stress urinary incontinence and Grade 2-3 anterior vaginal wall prolapse and found that the Burch colposuspension was better in controlling stress incontinence but that cystocele recurred in 34% of

patients. The cure rate for cystocele with anterior colporrhaphy was high (97%) but stress incontinence cure rate was very low. The authors concluded that neither operation was recommended for combined stress incontinence and advanced cystocele.

Gordon (Gordon et al 2001) [600] prospectively followed 30 patients short-term who underwent TVT at the same time as surgery for severe genitourinary prolapse. No patients had postoperative symptoms of stress incontinence despite 3 patients (10%) having positive postoperative stress tests. De novo detrusor overactivity occurred in 13% of subjects. A RCT compared types of anti-incontinence procedure performed with prolapse surgery, endopelvic fascia plication and TVT. (Meschia 2004) [40] (Level 1). This study included 50 women and demonstrated that adding a TVT results in higher 2-year objective continence rate than endopelvic fascia plication at the urethrovesical junction (92% vs. 56%, respectively;  $p < .01$ ). The subjective cure rates were 96% for TVT compared to 64% for suburethral plication. Time for resumption of spontaneous voiding, rates of urinary retention, de novo urge incontinence, and complications did not differ between the groups. Despite negative cystometrograms, de novo urge incontinence symptoms were reported in 12% of the TVT group compared to 4% of the suburethral plication group ( $p = .66$ ). Although not statistically significant, the authors recommend that data from a larger series are required to define the risk: benefit ratio between TVT and endopelvic fascia plication.

The TVT procedure combined with vaginal reconstruction resulted in 85% to 95% cure rates for urodynamic stress incontinence in a prospective cohort (Huang 2003) [278] and case series (Partoll 2002) [279]. Huang et al (Huang 2003) [278] reported urinary urgency and voiding dysfunction rates of 10% and 11%, respectively. Voiding difficulties and post void residuals of  $> 100$  ml were treated with urethral dilatation. The authors did not report any cases of long-standing urinary retention.

#### **b) Urgency incontinence with prolapse**

The effect of anterior vaginal wall prolapse on bladder function and the influence of surgical repair are much debated. Digesu et al (2007) [280] reported on a 12 month prospective cohort study of ninety three women who had a standard anterior fascial repair for cystocele. Post-operatively, urinary frequency resolved in 60%, urgency resolved in 70% and urge incontinence resolved in 82% illustrating that anterior repair appears to resolve the majority of overactive bladder symptoms. Similar findings were reported in a prospective cohort study of prolapse repair in elderly women by Foster RT Sr et al (2007) [281]. They also noted that vaginal reconstructive or obliterative surgery produced a similar improvement in urinary symptoms at 12 months after surgery.

## **CONCLUSIONS**

There is Level 2/3 evidence that when prolapse repair surgery is performed at the same time as a TVT to treat stress incontinence, the cure rate for the stress incontinence is not adversely affected.

There is Level 3 evidence that treatment of prolapse by constructive or obliterative surgery improves overactive bladder symptoms.

## **IV. COMPLICATIONS OF SURGERY FOR STRESS INCONTINENCE**

- 1. EVIDENCE**
- 2. INCIDENCE OF COMPLICATIONS**
- 3. PREVENTION OF COMPLICATIONS**
- 4. OPERATIVE EXPERIENCE**
- 5. CHOICE OF APPROACH**
- 6. OTHER RISK FACTORS**
- 7. COMPLICATIONS RELATED TO SUI SURGERY**

### **a) Intraoperative**

#### **1. URINARY TRACT INJURY**

##### **i) Urethra**

##### **ii) Bladder**

##### **iii) Ureter**

##### **iv) Bleeding and vascular injury**

##### **v) Bowel injury**

### **b) Postoperative complications**

#### **1. VOIDING DYSFUNCTION AND URINARY RETENTION**

#### **2. VAGINAL EXTRUSION AND URINARY TRACT EROSION**

#### **3. NERVE INJURY**

#### **4. BONE ANCHOR RELATED COMPLICATIONS**

#### **5. SEXUAL DYSFUNCTION**

#### **6. OTHER POSTOPERATIVE COMPLICATIONS**

#### **8. PERIURETHRAL BULKING AGENTS**

### **1. EVIDENCE**

There are very few randomized, prospective studies adequately powered to assess differences in complications between operative procedures. Because the reported incidence of most complications is quite low, adequate powering of randomized clinical studies would necessitate extraordinarily large numbers of patients. Current literature does not permit such an analysis although national registries may be one such source of this information in the future. Most of the available evidence is from case series, non-cohort comparative trials or underpowered randomized trials. Meta analysis and underpowered clinical trials may give some information on the incidence of particular complications, but comparing the relative risk of complications across various procedures of a similar nature is difficult and may be misleading based on available data.



The field of incontinence surgery, and especially stress urinary incontinence (SUI) surgery has rapidly transformed over the past several years. The types of SUI procedures being performed has evolved from transvaginal needle suspensions and retropubic suspensions to various types of slings, most commonly the midurethral polypropylene slings. This shift has implications for the types of complications seen in contemporary practice. Therefore the emphasis in this section will be in review of the midurethral sling procedure and its many derivatives. It is important to note that much of the data regarding these complications is immature. It is possible that over time the incidence of various types of complications or unforeseen additional types of complications may occur.

## 2. INCIDENCE OF COMPLICATIONS

The overall incidence of intraoperative and postoperative complications is difficult to ascertain. Much of the available literature derives from a single centre experiences, national registry data, case series or case reports. In addition, the reporting of surgical complications by individual investigators is not mandatory, is often selective, and is defined by the investigator. Furthermore, the incidence and type of complications reported in the literature are, for the most part, derived from academic medical centres. Complications arising in community practices may be wholly different. Central databases such as the FDA MAUDE website are voluntary and accurately determining complication rates based on such data is not possible for a variety of methodological reasons.[282]. In addition, there is no generally accepted standard categorization, or nomenclature for the reporting of surgical complications for urinary incontinence (UI) surgery although it has been suggested [283,24]. One such paradigm was developed by the AUA SUI Guidelines Panel which divided complications into 6 categories: transfusions, general medical, intraoperative, perioperative, subjective, and those complications requiring surgery [24]. Unfortunately this taxonomy has not been widely adopted. A system for the grading of severity of surgical complications has also been developed [284] and utilized in the UI literature [46] but it does not provide a mechanism for classification of specific complications in the genitourinary tract. Complications vary in severity and associated morbidity (i.e. a postoperative UTI vs. transvaginal erosion and extrusion of a synthetic sling material are not equivalent in severity but are weighted equally in the overall complication rate of a given procedure) As a result of these deficiencies an omission of the reporting of a given complication by an investigator is considered consistent with its lack of occurrence. Whether this method of accounting reflects accurately on the trial or on clinical practice is not clear. Finally, the definition of exactly what constitutes a complication is unclear. There are

particular complications that are dichotomous or categorical: they either occur or they do not (e.g.: bowel injury, urinary tract injury, sling extrusion). However, other potential complications such as bladder outlet obstruction and dyspareunia are graded on a spectrum and not well defined. This lack of standardization permits considerable variability in the reporting of complications. For example, excessive bleeding is considered by most surgeons to be a complication but some bleeding is commonly encountered in the performance of most anti-incontinence procedures. However, the quantity of bleeding that must occur for it to be considered a complication is not standardized. Bleeding as a complication has been defined variably in the literature as a volume of blood loss (e.g. >200cc), development of a postoperative hematoma, peri- or postoperative hypotension, the requirement for transfusion, or even hemorrhagic shock and death.

Notwithstanding the limitations noted above, the incidence of complications varies widely between studies. Case reports and case series likely underestimate the actual incidence of some complications especially major complications [285]. In some series for certain groups of patients undergoing UI surgery, the complication rate may approach 40-50% if UTI's and urgency symptoms are defined as complications [286,287]. The AUA SUI Guidelines Panel reported that each of the 6 categories of complications occurred in 2-16% of patients across the 4 types of procedures covered in the meta-analysis: slings, retropubic suspensions, transvaginal suspensions and anterior repair. In a review of midurethral sling procedures, Boustead et al noted that the complication rate in published series ranged from 1-40% [288]. Taub et al used the Nationwide Inpatient Sample (a national database in the US) of over 147,000 patients who underwent surgery for SUI from 1988 to 2000 and found an overall complication rate of 13% [289]. Waetjen et al estimated a complication rate of 18% from the 1998 National Hospital Discharge Survey and the 1998 National Census including data on over 135,000 patients undergoing surgery [223]. On review of a sampling of the Medicare database from 1999-2001, Anger et al found that 12.5% of patients undergoing a sling developed a surgical or urological complication in the first 3 months following surgery [221].

## 3. PREVENTION OF COMPLICATIONS

Although most complications related to the surgical treatment of female urinary incontinence are treatable and, for the most part reversible, the optimal scenario is to prevent or minimize the potential for an adverse outcome. Certain preoperative factors may influence the risk of intraoperative or postoperative complications. Most have not been studied in a controlled fashion.

#### 4. OPERATIVE EXPERIENCE

Operative experience with a given procedure has been cited as an important factor contributing to the risk of complications. Proper training and subsequent maintenance of skills is important not only in optimizing outcomes, but in minimizing complications. The number of cases necessary to gain competence with a given procedure is unknown and likely varies with the nature of the surgery, the learning environment and the skill of the surgeon. For the experienced and practicing surgeon, the NICE guidelines from the UK recommend that a minimum of 20 cases per year per surgeon for each incontinence procedure is necessary to maintain skills [290] this document further states that if fewer than 5 of a particular procedure are done by an individual surgeon per year, then local clearance and oversight, or alternatively referral to another centre may be necessary [290].

Kuuva et al reviewed a nationwide database on midurethral slings and noted that operative complications varied inversely with surgical experience (Level 3) [273]. These authors reported that the risk of bladder perforation during a transvaginal midurethral sling varied with the experience of the operating surgeon in doing the procedure. Surgeons performing more than 80 procedures had almost 50% fewer perforations than those with less than twenty cases experience and these authors also noted that complications decreased per surgeon after completing 15 procedures. McClennan et al reported that the risk of perforation of the urinary bladder during TVT decreased with increasing surgical experience in a residency training program (Level 3) [276]. In a prospective Dutch study of TVT procedures, there was an increased risk of complications in teaching hospitals as compared to non-teaching hospitals as well as an increased risk of complications during a surgeons second 10 procedures as compared to their first 10 procedures or >20 procedures (Level 2) [291]. Alternatively, Anger et al, in review of a large national database found no correlation between surgical experience and risk of surgical complications in patients undergoing SUI surgery (Level 3) [601].

#### 5. CHOICE OF APPROACH

The relative risks of each complication between the various types of surgery being performed, especially within a single category such as midurethral slings, regardless of approach (e.g. the risk of bleeding in a transobturator vs. suprapubic vs. transvaginal approach), is difficult to assess due to the small number of randomized controlled trials between procedures and the relative low frequency of the event (complications). In a large meta-analysis in 1997, the AUA SUI Guidelines Panel reported that slings and retropubic suspensions were associated with a higher risk of complications such as bleeding and obstruction than anterior repairs and needle bladder neck suspensions (Level 1) [24].

There are few prospective randomized trials comparing complications. Ward and Hilton compared Burch to TVT and found that the risk of intraoperative complications such as bladder perforation was higher in the TVT group whereas the risk of postoperative complications such as delayed voiding was greater in the Burch group (Level 1) [65]. The Urinary Incontinence Treatment Network (UITN) completed a randomized controlled trial comparing Burch colposuspension to autologous rectus fascia pubovaginal sling (Level 1) [46]. There was no overall difference in total serious adverse events between groups (13% vs. 10%,  $p=0.20$ , sling vs. Burch, respectively) but surgical interventions for the treatment of voiding dysfunction only occurred in the sling group (19 interventions in the sling group vs. none in the Burch group). Overall adverse events (including most commonly UTI's) occurred more often in the sling group. (63% vs. 47%,  $p<0.001$ , sling vs. Burch, respectively). A small prospective study compared autologous fascial sling to TVT in 53 patients with SUI and found no difference in complications between the groups at 6 months follow-up (Level 2) [166].

There have been a few randomized trials comparing some combination of TOT (transobturator), TVT (transvaginally placed retropubic tape), and SP (suprapubically placed retropubic) urethral tapes. Zhu et al found no difference in complication rates or urinary retention in 56 women randomized to either TVT or TOT (Level 2) [292] as did Lee et al with 120 patients quasi-randomized to either procedure [293]. Laurikainen and colleagues noted that a TOT approach was associated with more complications than TVT but this difference was not considered clinically significant by the authors [209]. However, Liapis et al noted more overall complications in patients undergoing TVT (11/46) as compared to TOT (2/43) in a randomized trial between these two procedures [208]. At a median follow-up of 9 months, Wang et al noted no significant difference in complications between 60 patients randomized to TOT or SP urethral tapes although there was a non-significant trend for increased thigh pain and vaginal extrusion in the TOT group (Level 2) [591]. In a prospective trial, David-Montefiore et al found similar complication rates in patients randomized to TVT (8/42) or TOT (5/46) although the types of complications differed between the groups (see below) [294].

With respect to a transobturator approach, two studies have demonstrated equivalently low complication rates between the outside-in vs. inside-out approach (Level 2) [295,296].

#### 6. OTHER RISK FACTORS

There are many patient factors which may potentially impact on the risk of complications in a given patient including aetiology and type of urinary incontinence, age, medical co morbidities, preoperative sexual function, the presence of associated conditions such

as vaginal prolapse, and prior abdominal, pelvic or anti-incontinence surgery. In one prospective study of over 800 patients undergoing TVT, Schraffordt Koops et al noted an overall 6.2% incidence of complications and identified several risk factors including menopausal state, previous prolapse surgery (but not prior incontinence surgery), mode of anaesthesia, and having the procedure done in a teaching hospital (Level 2) [291].

Identifying preoperative patient risk factors such as prior surgery, age, and obesity that consistently predict for intraoperative and postoperative complications has also been difficult. Much of the existing literature is conflicting (Level 3) [297]. For example, some authors have found that prior pelvic or incontinence surgery predicts for intraoperative bladder injury during midurethral sling (Level 2-3) [286, 298, 206, 257], while others have not (Level 2) [301]. This variability may be due to the type of prior SUI surgery: prior retropubic surgery such as Burch or MMK may lead to retropubic scarring and a risk of bladder injury whereas a prior transvaginal operative such as a Kelly plication wherein the retropubic space is not violated, may not [257]. Advanced age is not a contraindication to anti-incontinence surgery.

However surgery in the advanced elderly (>80 y.o.) may be associated with some increased morbidity as compared to the “young” elderly (Level 3) (65-80 y.o.) [299] and may be associated with higher rates of postoperative urge incontinence, bladder outlet obstruction and surgical failure as compared to younger patients (Level 3) [300]. Rogers et al demonstrated no increased risk of intraoperative or postoperative complications in obese patients (BMI>30) as compared to the non-obese patients undergoing a variety of SUI surgeries in a prospective nested cohort study.(Level 2) [301] This supports the conclusion of other prior studies [233,302]. One study noted that individuals with a BMI>26.5 were at increased risk of bladder perforation during TVT but that overall outcomes were not affected [303].

## 7. COMPLICATIONS RELATED TO SUI SURGERY

### a) Intraoperative Complications

#### 1. URINARY TRACT INJURY

During SUI surgery, the urethra, bladder or, much more rarely, the ureters may be injured. The key to the management of each of these injuries is immediate recognition and repair. Long term sequelae resulting from unrecognized urinary tract injury can be devastating to the patient.

##### i) Urethra

Intraoperative urethral injury during UI surgery is rarely reported. It may occur during the initial transvaginal dissection, during trocar placement for midurethral

sling procedures, needle placement for transvaginal suspensions, or during cystocele repair. Failure to recognize the injury or failure to repair it properly risks urethrovaginal fistula, erosion of sling material into the urethral lumen postoperatively, infection, and other potential problems (Level 4). The risk of urethral injury may be as high as 4 fold greater in the transobturator approach as compared to the TVT/retropubic approach [290] however this data is based on a single literature review and thus indirect comparisons and not randomized control trial data.

In the event of a planned synthetic sling in the setting of a concomitant intraoperative urethral injury, it is probably advisable to repair the urethra and abort the sling procedure until the urethra is completely healed (Level 4).

An autologous sling may be considered a safer alternative than a synthetic sling at the time of a urethral injury as an anti-incontinence procedure but there is little data to support this notion (Level 4). The urethra is rarely injured during retropubic surgery as the middle and distal thirds are protected by the symphysis pubis.

##### ii) Bladder

The potential for bladder injury may vary with the choice of operative approach. Albo et al reported a trend toward more bladder injuries in the colposuspension group as compared to the sling group (10/329 vs. 2/326, colposuspension vs. sling respectively) in the UITN study [46]. The risk of bladder injury during midurethral sling is probably higher with a retropubic approach as compared to a transobturator approach although randomized trial data are minimal in this regard (**Figure 8**).



**Figure 8 : Mesh erosion into the bladder following TVT**



In one literature review, the risk of bladder injury may be as much as 6 fold higher in the TVT/retropubic approach as compared to the transobturator approach [290]. The incidence of bladder perforation during TVT has been reported in 0-8% of patients (Level 3) [273,317,291,206,65]. Hodroff et al reported an overall bladder perforation rate of 6.7% in 445 patients undergoing a SP midurethral tape procedure and Deval et al reported an incidence of 10.5% in 104 patients (Level 3) [304, 286]. Davila et al reported no bladder perforations in over 200 patients undergoing a TOT sling (Level 3) [305].

Barber et al retrospectively compared over 200 patients undergoing TVT to a similar number of patients undergoing TOT (Level 3) [306] and found that the incidence of bladder perforation in the TVT group was 5% while there were no such injuries in the TOT group. Several small prospective RCT's have reported a trend towards a greater risk of bladder perforation during TVT as compared to TOT (Level 2) [209, 208,307]. Nevertheless, there are multiple reports of bladder injury during transobturator midurethral slings [308,309] and thus this potential complication must be considered.

The relative risk of bladder perforation with a transvaginal vs. suprapubic approach to retropubic midurethral slings is, as of yet, unclear. While one retrospective study noted a high bladder perforation rate with a suprapubic approach (29% vs. 4%, suprapubic vs. transvaginal, respectively) (Level 3) [310], others have not (Level 2) [200].

In one small randomized prospective trial comparing transobturator to retropubic midurethral slings, bladder perforation was noted only in the retropubic cases (4/42, 9.5%) whereas vaginal injury was noted only in the transobturator cases (5/46, 10.9%) [294].

Redo incontinence surgery may be associated with a higher risk of urinary tract injury in patients undergoing midurethral sling surgery. Jeffry et al reported a bladder perforation rate during TVT of 71.4% vs. 7.6% in patients with prior surgery vs. those without (Level 3) [298]. Likewise, in patients undergoing SPARC, Deval et al reported a 36.6% vs. 7.5% urinary tract injury rate in those with vs. those without a history of prior surgery (Level 3) [286]. The risk of bladder perforation in the Austrian TVT national registry was 4.4% in patients with prior surgery but only 2% in those without prior surgery (Level 3) [206]. However, LaSala et al reported that prior abdominal hysterectomy or BMI >26.5, but not prior anti-incontinence surgery, was associated with an increased risk of intraoperative cystotomy during TVT (Level 3) [303]. Nevertheless, in one series, the surgical results in those with an intraoperative bladder perforation during TVT appear to be no different from those without such a complication provided that the perforation is recognized intraoperatively and corrected

(Level 3) [303]. It is possible that the type of prior surgery has a significant impact on the risk of bladder perforation with such operations as Burch colposuspension in which there is considerable dissection in the retropubic space posing a potentially greater risk than prior anterior repair where no such dissection is performed (Level 3) [257]

### *iii) Ureter*

Ureteral injury during incontinence surgery is very uncommon. The ureter may be kinked or obstructed during Burch or MMK procedures or during bladder neck sling procedures. With the advent of midurethral slings, these injuries are rare given the expected location of the sling at the level of the midurethra. In the UITN trial of Burch vs. autologous fascial sling, there were 2 ureteral injuries and both occurred in the Burch group [46].

### *iv) Bleeding and vascular injury*

The risk of bleeding during SUI surgery can be minimized, but not entirely eliminated by good operative technique. Multiple blood vessels traverse the deep pelvis including large venous channels in the retropubic space. Named vessels in the obturator fossa, along the pelvic sidewall including the iliac vessels, and within the vascular pedicle of the bladder are at risk for injury especially during vaginal incontinence surgery due to lack of direct visualization of these structures during passage of trocars or needles (**Figure 9**).

Major vascular injury can quickly lead to life threatening haemorrhage if not recognized intraoperatively and may result in large retropubic hematomas postoperatively [311,312]. Leach et al reported bleeding complications requiring transfusion in 5% of colposuspensions, 4% of slings, 3% of needle suspensions and 3% of anterior repairs. (Level 1) [24]



**Figure 9 : Abdominal wall haematoma after laparoscopic surgery**

These differences were not statistically significant. In a series of over 5000 midurethral slings reported on by the Austrian Working Group for Urogynaecology, bleeding problems were reported in 2.7% of cases (Level 3) [313]. Only 0.8% of patients required intervention for bleeding with the vast majority of cases managed conservatively without operative intervention. Less than 1% of patients required transfusions. Kuuva et al reported a 1.9% incidence of bleeding >200cc in over 1400 TVT cases (Level 3) [273]. RCT's comparing TOT to TVT and SP urethral tapes show no significant difference in bleeding complications between approaches (Level 2) [307,208,209]. There was no significant difference in complications related to bleeding between the colposuspension group and the sling group in the UITN report from Albo et al (3/329 vs. 1/326, p=0.62, colposuspension vs. sling respectively) [46].

#### **v) Bowel injury**

There exist multiple reports of bowel injury during urinary incontinence surgery [314,308,304]. Fortunately this is a rare and very infrequently reported complication. Bowel injury may occur during the retropubic dissection for a Burch or MMK especially in reoperative surgery, during entry into the retropubic space during an autologous pubovaginal sling, or during passage of needle passers or trocars during midurethral slings. These can be devastating complications leading to sepsis, abscess and even death [308].

#### **b) Postoperative complications**

##### **1. VOIDING DYSFUNCTION AND URINARY RETENTION**

Bladder outlet obstruction (BOO) may occur following SUI surgery. This presents as prolonged complete urinary retention, persistently elevated post-void residual urine volume or, as variably bothersome and poorly categorized lower urinary tract symptoms including combinations of recurrent urinary tract infections, obstructive symptoms and urinary urgency or urge incontinence.

Historically the prevalence of postoperative voiding difficulties lasting greater than 4 weeks occurs in 3-7% of patients undergoing Burch procedures, 4-8% of those undergoing transvaginal needle suspensions and 3-11% of pubovaginal slings [24]. Permanent urinary retention was estimated to be <5% across all procedures by these same authors.

The prevalence of voiding dysfunction, including urinary retention and de novo urgency and urge incontinence, following midurethral slings ranges from approximately 2%- 25% (Level 2-3) [315-317, 320,367,318,319,295,286,298,206,205]. Surgical intervention for voiding dysfunction and urinary retention has been reported in 0-5% of patients undergoing midurethral slings (Level 2-3) [304, 206,319,295,367].

Randomized prospective studies have shown short term voiding difficulties following TVT appear less likely than following Burch (Level 1) [65] and pubovaginal slings (Level 2) [166]. Dietz found TOT to be less "obstructive" than TVT based on flow rates and ultrasound (Level 3) [321]. In one multicenter retrospective study, transobturator slings had fewer "obstructive" complications than retropubic midurethral slings (Level 3) [322] and another retrospective study compared TVT to TOT and found that fewer patients in the TOT group required urethrolisis or anticholinergic medications in the postoperative period implying less obstruction (Level 2) [306]. Alternatively, one randomized trial comparing SP midurethral tapes to TOT demonstrated no difference in postoperative voiding dysfunction (Level 2) [204].

The diagnosis of urethral obstruction following SUI surgery is difficult and based on a combination of clinical parameters. In some patients, cystoscopy and videourodynamics may be helpful. However, there is no universally agreed method of making a diagnosis of postoperative urethral obstruction which prevents a true assessment of the incidence of this complication.

Management options for prolonged postoperative voiding difficulties include repeated voiding trials, initiation of intermittent urethral catheterization, and incision of the sling or urethrolisis. As many cases of postoperative voiding dysfunction will spontaneously resolve, the ideal timing for surgical intervention has not been defined. Early intervention may result in high rates of recurrent SUI in patients in whom the voiding dysfunction may have resolved spontaneously given enough time. Alternatively, subjecting the patient to ongoing irritative lower urinary tract symptoms, UTI's or CIC due to ongoing obstruction is not optimal. Some authors have recommended conservative therapy for postoperative voiding dysfunction for up to 3 months prior to attempting surgical revision [323]. However, a prolonged time to intervention for BOO may be associated with long term, potentially irreversible bladder dysfunction even following successful urethrolisis [324, 325].

Transvaginal sling incision is often successful in reversing obstruction from a pubovaginal or midurethral sling (Level 2) [326-328]. For patients who fail transvaginal incision, or who underwent a non-sling procedure as the cause for their BOO, a urethrolisis may be performed [329,330]. Via a transvaginal or retropubic approach [221,329,331], the retropubic space is entered and the urethra is sharply dissected off the posterior surface of the symphysis pubis and freed from the surrounding scar. The limbs of the sling or other retropubic attachments are isolated and divided in the retropubic space. Lateral attachments to the pelvic sidewall are incised as needed for those who previously underwent a Burch or paravaginal repair. A transvaginal, suprameatal approach to urethrolisis has also been described and may be



particularly applicable to those patients previously undergoing an MMK [331].

Recurrence of SUI symptoms following urethrolisis or sling incision may occur in 15-20% of patients [328,332].

## 2. VAGINAL EXTRUSION AND URINARY TRACT EROSION

Vaginal extrusion refers to the finding of exposed sling material in the vaginal cavity postoperatively, whereas erosion implies the finding of material within the lumen of the urinary tract at some time interval postoperatively (**Figure 10**) which was clearly documented as not being within the urinary tract at the time of surgery. Both extrusion and erosion may lead to long term voiding dysfunction despite removal of the sling material.[333].

Extruded material may be located in the midline at the incision line or at the anterolateral vaginal wall. Midline extrusions imply wound dehiscence or defective healing whereas lateral extrusions may be due to an unrecognized vaginal wall perforation or injury at the time of sling placement (Level 4) [334].

Extrusion of material may be related to surgical technique, host factors, wound healing, infection, or the physical properties of the implanted material such as pore size or monofilament vs. multifilament construction [335,336]. Pore size or the specific weave of a mesh may be related to the intrinsic ability of a material to resist infection by allowing migration of host fibroblasts and macrophages into the interstices of the mesh to eliminate bacteria [336]. Certain woven



**Figure 10 : TVT mesh extrusion on anterior vaginal wall**

mesh products may have a pore size or interstices below a critical size which may predispose to infection. There is a paucity of randomized trials comparing monofilament to multifilament (polyfilament) mesh. One randomized trial found 9 extrusions in a multifilament sling group as compared to none in the monofilament group (TVT) (Level 2) [203] and another trial reported higher extrusion rates with a multifilament as compared to two other monofilament products [588]. A case control study comparing a monofilament to a multifilament mesh reported a several fold increase in urethral erosions in the multifilament group as compared to the monofilament group [337]. However, Rechberger et al noted no difference in extrusion rate in an RCT comparing monofilament to multifilament mesh. (Level 2) [201]. Several case series have suggested that the risk of extrusion with multifilament or other types of treated mesh is significant and may occur in 9-20% of cases (Level 4) [338-342,588]. The reported rate of mesh extrusion from case series using monofilament sling materials has been reported as between 0-5% [291,273,203,65,343,304]

Extrusions should be treated expeditiously. Some small extrusions may heal with conservative management including the application of topical oestrogen creams (Level 4) [343]. The size of an extrusion which can be managed non-operatively is not well defined nor is the time frame after which surgical intervention should be pursued. Larger extrusions can be managed with copious irrigation and secondary closure in the operating room. Some patients with large extrusions which are unable to be secondarily closed or who have already failed secondary closure should undergo excision and removal of the extruded sling (Level 4).

Urinary tract erosion may occur with synthetic, biologic or autologous materials [344,345]. The risk of sling erosion into the urethra is extremely low. In several national databases, the urethral erosion rate for TVT has been reported to be less than 1% [346,273, 206,291]. One retrospective series demonstrated no urethral injuries with TOT-I or TOT-O [334]

This complication is managed operatively. Whether urinary tract erosion occurs as a result of a "missed" urinary viscus perforation at the time of surgery, or occurs as a result of migration of the material into the urinary tract sometime following surgery, is unclear. Patients may complain of irritative lower urinary tract symptoms, recurrent UTI's, haematuria, dysuria as well as pelvic pain. The definitive diagnosis of urinary tract erosion is usually made endoscopically and treatment may involve endoscopic [347,348] or open removal of the eroded mesh.

## 3. NERVE INJURY

Several nerves traverse through the deep pelvis as well as superficially within the lower abdominal soft

tissues. These nerves are at risk for injury during female incontinence surgery during positioning of the patient or during the surgical procedure.

Lithotomy position may result in stretch or compression injury to the femoral nerve as can retractor placement during retropubic UI surgery. Femoral nerve compression may occur at the level of the inguinal ligament due to flexion of the hip joint [349]. This results in sensory changes to the anterior thigh or in more severe cases weakness of hip flexion. Severe abduction and external rotation of the thigh should be minimized during positioning to avoid this complication. The peroneal nerve can be injured by direct compression while in the lithotomy position. Lateral direct pressure on the peroneal nerve between the stirrup at the lateral aspect of the knee joint and the fibular head for a prolonged period of time may result in a peroneal nerve palsy and foot drop [349]. This injury may also occur with compression of the fibular head against the stirrup holder, especially candy cane stirrups as the leg rotates externally after placement in the holders.

The ilioinguinal and iliohypogastric nerves may be injured by sling harvest during autologous rectus fascia pubovaginal sling, trocar placement or dissection [350,367].

#### **4. BONE ANCHOR RELATED COMPLICATIONS**

Bone anchors (BA) were popularized as an alternative method of suture fixation during stress urinary incontinence surgery such as pubovaginal slings and transvaginal needle bladder neck suspensions. Rackley et al estimated the prevalence of BA related infections in female pelvic reconstructive procedures as approximately 0.6% [351]. However, the complications associated with BA's can be devastating including pelvic abscess and osteomyelitis of the symphysis pubis. There are numerous reports of bone anchor related complications associated with female incontinence surgery in the urologic, gynaecological and orthopaedic scientific literature [352-355]. Once diagnosed, osteomyelitis related to BA's requires operative exploration and removal of the bone anchor.

#### **5. SEXUAL DYSFUNCTION**

Postoperative female sexual dysfunction (FSD) was reported in between 2-8% of female patients undergoing SUI surgery in the AUA Female SUI Guidelines Panel [24]. The difference between procedures was not statistically significant. There are several questionnaires that have been utilized to assess FSD [356]. Use of these disease-specific questionnaires may yield a higher incidence of FSD than previously reported in many series which may be up to 20% [356,357] however not all contemporary series report such findings.[358].

Dyspareunia is one form of sexual dysfunction and it

may occur following UI surgery. Vaginal anatomy is altered by SUI surgery. The vaginal axis can be shifted changing the angulation of the vaginal canal. Circumferential narrowing of the vagina may occur due to excessive trimming of vaginal wall during prolapse surgery or as a result of aberrant scarring. Dissection along the anterior vaginal wall may result in nerve injury and neuroma formation. Sling erosion may also result in dyspareunia. Other poorly understood factors contributing to postoperative sexual dysfunction may exist. For example in some series 4-5% of patients following TVT or IVS slingplasty experienced decreased libido [359,356]. The reason for this decreased libido is unclear.

#### **6. INFECTION AND UTI**

Multiple cases of pelvic abscesses have been reported with anti-incontinence surgeries including midurethral slings [360,361,363,282,364-365]. These consist mostly of case reports (Level 4).

There is inconsistent reporting of the prevalence urinary tract infection following anti-incontinence surgery. This may be due to issues with definitions and cause and effect.

#### **7. GENERAL MEDICAL COMPLICATIONS AND OTHER POSTOPERATIVE COMPLICATIONS**

The incidence of significant morbidity from non-urinary tract medical conditions is unknown. As with any surgical procedure, there exists an undefined risk due to anaesthesia, associated cardiac and pulmonary morbidities such as postoperative myocardial infarction or pulmonary embolus. Older age and medical co morbidities may be associated with an increased risk of general medical and non-urological complications in older patients undergoing UI surgery as compared to younger patients [300].

Likewise the risk of death is unknown as this is an exceedingly rare complication in UI surgery. The AUA SUI Guidelines Panel estimated the risk of death following anti-incontinence surgery as 5 /10,000 cases based on data from hysterectomy series [24].

Urinary fistula following SUI surgery is quite rare. Nevertheless, an unrecognized and unrepaired intraoperative injury to the ureter, bladder or urethra may result in ureterovaginal, vesicovaginal or urethrovaginal fistula.

De novo vaginal prolapse may occur following anti-incontinence surgery and has been associated with colposuspension procedures including vault prolapse and posterior vaginal wall prolapse.

#### **8. PERIURETHRAL BULKING AGENTS (Figure 11)**

In general, the morbidity associated with periurethral injectable agents is low. UTI, short term voiding dysfunction including urinary retention and haematuria



**Figure 11 : Silicone collection lateral to external urethral meatus**

have been reported with all of the periurethral injectable agents. Stothers et al looked at complications related to intraurethral bovine collagen injection in a large series of patients (Level 3) [366]. In 337 patients injected with intraurethral collagen, approximately 20% of patients had at least one minor complication. The most common reported complication was de novo urge incontinence in 12.6%, followed by haematuria in 5% and urinary retention in 1.9%. Other bulking agents have demonstrated similar adverse event trials (Level 2) [148,144,150,149].

With respect to approach, periurethral injection has been noted to be associated with more complications including urinary retention and postoperative voiding dysfunction as compared to transurethral injection of bulking agents in one randomized trial of a dextran/hyaluronic acid compound (Level 2) [149,144].

Randomized controlled trials have compared bovine collagen to carbon coated beads as well as calcium hydroxylapatite. Lightner et al demonstrated a similarly minimal long term complication rate between collagen and carbon coated beads with a higher incidence of short term urinary retention and urgency in the carbon coated bead group (Level 1) [144]. Mayer et al noted no difference in short or long term complications in a randomized prospective trial comparing collagen and calcium hydroxylapatite (Level 1) [150]. Finally, there was no significant difference in short or long term complications in a randomized trial comparing porcine collagen to silicone (Level 2) [148].

Periurethral bulking agents including silicone [140] and collagen [141] have been compared to surgery in 2 randomized prospective trials. In both trials morbidity due to surgery was significantly greater than that associated with the injectable agent (Level 2).

Distal and systemic migration of polytef [368,369], and carbon coated beads [370] has been reported. The long term ramifications of these synthetic materials in the lymph nodes, lungs, brain and other organs are unknown. One bulking agent has been noted to have a high rate of erosion into the urethral lumen and has been recently withdrawn from the US market-place.[371]

## V. SURGERY FOR DETRUSOR OVERACTIVITY

The presumed aetiology of overactive bladder is detrusor overactivity [372]. Symptomatically, only 1/3 of patients with overactive bladder have associated urinary incontinence [373]. Many of these patients can be successfully treated with a combination of non-surgical measures including behavioural modification, pelvic floor physiotherapy and pharmacological therapy (see chapter on *Conservative Management of Urinary Incontinence*). Surgical therapy of non-neuropathic overactive bladder incontinence is generally reserved for those patients who have failed an adequate trial of these measures [374,375]. Overall, there are few studies on the surgical therapy of non-neurogenic detrusor overactivity urinary incontinence.[376,377]

Surgical interventions for urinary incontinence related to neurogenic detrusor overactivity incontinence are covered elsewhere (see chapter on *Neuropathic Bladder*).

### 1. ENDOSCOPIC APPROACHES

#### a) Endoscopic bladder transaction

Endoscopic bladder transaction is modelled after an open procedure, designed, in part to denervate the bladder by circumferential endoscopic incision proximal to the bladder neck. There are few reports of its use and this procedure is now rarely, if ever, performed.

**Level I evidence:** There is no Level 1 evidence regarding this modality in the therapy of non-neurogenic detrusor overactivity incontinence.

**Other evidence:** Parsons et al reported endoscopic bladder transaction as an effective technique of treating symptomatic bladder instability (Level 4 evidence) [378]. Subsequent reports (Level 4 evidence) [379,380] have been less favourable.

#### b) Hydrodistension or Bladder Overdistension

Bladder overdistension was originally described by Helmstein et al for the treatment of bladder cancer [381] but has also been cited as potential therapy for the treatment of some types of voiding dysfunction, including interstitial cystitis. Several reports have described its application towards the treatment of



detrusor overactivity. In practice, this procedure is performed under general or regional anaesthesia and utilizes a hydrostatic column of fluid under high pressure infused into the urinary bladder and left indwelling for a variable period of time. The mechanism by which this therapy purportedly treats detrusor overactivity is not well understood.

**Level I evidence:** There have been no randomized controlled trials, double blind trials or cohort studies which have examined the effects of bladder overdistension or hydrodistension for the treatment of non-neurogenic detrusor overactivity incontinence.

**Other Evidence :** There are only a few reports on hydrodistension for the therapy of detrusor instability or non-neurogenic detrusor overactivity incontinence. The existing literature consists of primarily small retrospective case series with brief follow-up and subjective outcome parameters (Level 4 evidence).

Of the few favourable reports on hydrodistension for urinary incontinence, Ramsden reported that 41/51 patients (80.4%) had substantial improvement or were free of urinary symptoms at a follow-up of 13 months [382]. Dunn et al noted that 19/20 patients with urge incontinence or severe urgency and frequency were either improved or cured following bladder distention [383]. Corroborative objective outcomes data such as pad tests or voiding diaries were lacking in both of these studies. In contrast, Delaere and colleagues reported on 63 patients with involuntary bladder contractions on cystometry and urge incontinence undergoing prolonged bladder distention [384].

Results were tabulated according to symptomatic outcome. Continence was not a primary outcome measure. At 1 year follow-up 11% of patients were cured and 21% improved. Whitfield noted that none of 11 patients with detrusor instability treated with a classical Helmstein balloon bladder overdistension "reverted" to a normal cystogram although 6/11 noted some symptomatic improvement [385]. Poor results were also seen by Pengally and colleagues in whom only 4/46 patients noted symptomatic improvement following hydrodistention [386]. Of the 43 patients undergoing postoperative urodynamics in this study, none had "conversion" to a stable detrusor on cystometry.

Long-term follow-up studies demonstrating an objective or durable response to this modality of therapy for detrusor overactivity incontinence are lacking. Outcome measures have included mostly subjective patient assessments done in a retrospective fashion. Validated general or disease specific quality of life instruments have not been utilized to assess outcomes in these patients.

Bladder rupture, haematuria, infection, voiding dysfunction, and urinary retention are potential risks of bladder overdistension.

### **c) Transvesical Phenol injection**

Transvesical phenol injection is performed by endoscopic injection of a 5%-6% aqueous phenol solution in the region of the trigone of the bladder. The mechanism by which phenol exerts its favourable effects is purported to be via chemical denervation (neurolytic agent) [387].

**Level I evidence:** There are no randomized, double blind, placebo controlled studies that have examined the efficacy of subtrigonal phenol or compared it to another therapy for detrusor overactivity incontinence.

**Other evidence:** Several uncontrolled studies have examined the effects of subtrigonal phenol injection for the treatment of both non-neurogenic and neurogenic detrusor overactivity (Level 4 evidence). Initial studies suggested that this therapy was safe and effective in the short term with response rates of between 58-83% [388-391]. Better response rates were seen in neurogenic as compared to non-neurogenic voiding dysfunction, especially in patients with multiple sclerosis [389,390]. In one study, neurogenic bladder patients had a markedly greater response rate (82%) as compared to younger (<55 years old) non-neurogenic patients (14%) [391]. Subsequent studies with longer-term follow-up have not reproduced these results. Chapple and colleagues reported that only 4 out of 24 patients derived any ongoing benefit from phenol injection at 6 months follow-up [392], whereas Ramsay and colleagues reported a subjective response rate of only 14% in 36 patients at a mean follow-up of 13.7 months [393]. Wall et al reported a 29% initial response rate with all patients eventually failing at up to 4 years follow-up [394]. A similar long term failure rate was seen by Rosenbaum et al where only 1 out of 60 patients maintained a satisfactory result at 2 years [395].

Overall an 11.3% complication rate has been attributed to subtrigonal phenol injection including urinary retention, fistula and significant hematuria [392].

#### **Recommendation:**

**Current evidence suggests that women with refractory non-neurogenic detrusor overactivity do not gain long term benefit from endoscopic bladder transaction, bladder overdistension, or transvesical phenol injection. Clinical use of these modalities is not recommended for this indication. (Grade C)**

## **2. OPEN SURGICAL INTERVENTIONS**

### **a) Ingelman-Sundberg Denervation**

In 1959 Ingelman-Sundberg described an operation for the treatment of urge incontinence that selectively divided the preganglionic pelvic nerves near the inferior surface of the bladder through a transvaginal approach.



This involved considerable dissection near the cervix and bilateral transection of the pelvic nerves in this region.

**Level I evidence:** There have been no randomized controlled trials, double blind trials, sham-controlled studies, or cohort studies which have examined the effects of Ingelman-Sundberg denervation for the treatment of non-neurogenic detrusor overactivity incontinence.

**Other evidence:** Hodgkinson et al reported good results with this procedure in a case series of 23 patients, with 12 patients subjectively cured and an additional 9 improved (Level 4 evidence) [396]. The results of a modified Ingelman-Sundberg procedure by Cespedes and colleagues suggested a 64% cure of urge incontinence in carefully selected patients at a mean follow-up of 14.8 months [397]. In this case series (Level 4 evidence) the authors preselected the 25 patients based on a satisfactory clinical response to a transvaginal injection of local aesthetic in the region of the trigone. Westney and colleagues reported long term results with the same modified Ingelman-Sundberg procedure in a case series of 28 women (Level 4 evidence) [398]. Using the same preselection criteria as Cespedes et al, these authors noted a 54% cure of urge incontinence and a 68% cure/improved rate at a mean follow-up 44.1 months.

One randomized prospective trial compared 96 patients with mixed urinary incontinence treated with a transobturator midurethral sling (TOT) alone vs. those treated with a TOT combined with an Ingelman-Sundberg procedure. Objective surgical response rate was significantly higher in the TOT plus Ingelman-Sundberg group than in the TOT alone group (84.8% vs. 62.8%;  $p=0.019$ ) [399]. Complications in both groups were similar although operative times were longer in the combined surgery group.

Complications associated with the Ingelman-Sundberg procedure have included ongoing voiding dysfunction, bleeding, and transient urinary retention.

### **b) Sacral rhizotomy**

This procedure is primarily performed in the neuropathic bladder population and is discussed further elsewhere (See *chapter on Neuropathic bladder*).

### **c) Enlargement (augmentation) cystoplasty**

#### **1. ENTEROCYSTOPLASTY**

Augmentation cystoplasty has been used for many years with varying degrees of success for refractory detrusor overactivity and related incontinence. Indications for enterocystoplasty (other than non-neurogenic detrusor overactivity) include small capacity bladders due to fibrosis, tuberculosis, radiation, or chronic infection, neurogenic detrusor overactivity,

poor bladder compliance, as well as others [400-403]. Virtually any portion of the GI tract can be utilized for enterocystoplasty with each segment having its own unique favourable properties as well as inherent complications [403,404]. There is no ideal segment for all cases. Incorporation of bowel into the lower urinary tract results in decreased bladder contractility and an interval increase in the volume to first involuntary bladder contraction during cystometry. Technically, the surgeon must be aware that the selected bowel segment should contain a suitable length of mesentery to reach into the deep pelvis for a tension free anastomosis between bowel and bladder. During enterocystoplasty, there is no general agreement on whether it is more favourable to bivalve the bladder sagittally or transversely. However, it is ideal to create the broadest possible opening in the bladder and thereby create the widest possible anastomosis between bladder and bowel resulting in the most spherical configuration possible. The bowel is divided and detubularised on its antimesenteric side prior to anastomosis to maximally reduce peristaltic contractions. The goal of enterocystoplasty is to create a high capacity, low-pressure reservoir during the filling/storage phase of the micturition cycle. When successful, and properly combined with other concomitant reconstructive procedures (i.e. uretero-neocystostomy, slings, artificial urinary sphincters, etc.), enterocystoplasty protects the upper urinary tract from pressure-related injury, infection and reflux while ideally providing complete urinary continence.

**Level 1 evidence:** There have been no randomized controlled trials, double blind or sham-controlled trials or cohort studies which have examined the effects of enterocystoplasty for the treatment of non-neurogenic detrusor overactivity incontinence or directly compared it to another therapy for the same indication.

**Other evidence:** There are only a small number of reports in the literature that have examined the results of enterocystoplasty in adult patients with non-neurogenic detrusor overactivity incontinence. These include only case series (Level 4 evidence). One series comprised solely females [405] with the remaining series including both males and females as well as varying numbers of neuropathic bladder patients [379, 406-412] (See Table 8). Outcome measures have included mostly non-validated questionnaires and subjective patient assessments. Validated general or disease specific quality of life instruments have not been widely utilized to assess outcomes in these patients.

Awad et al reported on a series of 51 female patients undergoing augmentation cystoplasty for refractory non-neurogenic bladder related incontinence [405]. 18% of patients continued to have disabling symptoms of urinary incontinence, and only 53% of patients classified themselves as "happy" with the outcome of the surgery. One series noted a deterioration in

outcomes over time [376]. In this mixed series, symptomatic improvement was reported in 83% of non-neurogenic patients at 3 months postoperatively, but decreased to just 58% at last follow-up (mean follow-up 38 months). In contrast, 92% of neuropathic bladder patients in this series reported a “good” or “moderate” result at last follow-up. Similarly, Herschorn and colleagues reported a very high degree of patient satisfaction in a series composed of only neuropathic bladder patients with all 59 patients reporting that they were delighted, pleased or mostly satisfied with the surgery [377]. The reasons for apparent superior patient satisfaction in neuropathic patients as compared to non-neuropathic patients are unclear.

#### **d) Auto augmentation**

As an alternative to enterocystoplasty especially in children with neuropathic bladder, auto augmentation of the bladder was initially described by Cartwright and Snow [413,414]. Auto augmentation may be performed by incision (detrusor myotomy) or excision (detrusor myomectomy) of a portion of the detrusor muscle. Either technique purportedly creates an iatrogenic bladder mucosal “bulge” or pseudodiverticulum and an increase in the storage capacity of the bladder with a concomitant decrease in storage pressures. The reported advantages of detrusor auto augmentation over enterocystoplasty is the avoidance of complications related to the use of bowel in the urinary tract including malignancy, mucous formation, stones, surgical morbidity related to opening and reanastomosis of the GI tract, and metabolic acidosis [375,415, 403].

**Level I evidence:** There have been no randomized controlled trials, double blind trials or cohort studies which have examined the effects of enterocystoplasty as a treatment for non-neurogenic detrusor overactivity incontinence.

**Other evidence:** There are few studies on auto augmentation in the adult non-neurogenic population (See Table 8). One small study of 5 patients with urge incontinence showed promising results in all patients at the initial postoperative visit, but clinical deterioration and failure occurred in 4 of the 5 patients at 3 months follow-up [416] (Level 4 evidence). Mean bladder capacity increased but mean volume to first unstable bladder contraction decreased. 4 of the 5 patients continued to have involuntary bladder contractions on cystometry. One retrospective study compared detrusor myomectomy to enterocystoplasty in 61 patients [412]. The population under study included both men and women with neurogenic and non-neurogenic voiding dysfunction. These authors reported comparable clinical success for the two procedures however there was a 22% incidence of serious complications in the 27 patients undergoing enterocystoplasty, compared to only 3% of the 33 patients undergoing detrusor myomectomy.

Long term follow-up of auto augmentation in children with neurogenic bladder has demonstrated disappointing results [417,418]. This has been attributed to eventual fibrosis of the pseudodiverticulum [415]. In an attempt to improve long-term outcomes with this procedure and create a biological “backing” and blood supply for the pseudodiverticulum, a number of variations of this procedure have been described. These variations have included the use of demucosalized bowel segments, stomach, peritoneum and rectus abdominis muscle [415,419-423]. Long-term follow-up demonstrating favourable clinical results with these variations is lacking.

#### **e) Tissue engineering**

Various tissue engineering techniques have been utilized in an attempt to create a suitable alternative to enterocystoplasty or autoaugmentation [424,425]. Many of these techniques rely on the use of native urologic tissues either partially or fully. Techniques have included the use of foetal tissues as well as collagen matrices overgrown with transplanted cells especially autologous cells.

**Level I evidence:** There have been no randomized controlled trials, double blind trials or cohort studies which have compared tissue engineered bladders in humans to any other technique for the treatment of non-neurogenic detrusor overactivity.

**Other evidence:** There are no published trials using tissue engineering techniques for bladder reconstruction in humans in the non-neurogenic detrusor overactivity population. One case series of 7 patients with neurogenic bladder due to myelomeningocele demonstrated modest success with tissue engineered autologous bladder constructs. (Atala, 2006) [426] (Level 4).

#### **f) Urinary diversion**

Urinary diversion away from the bladder is rarely needed for the treatment of non-neurogenic detrusor overactivity. This is usually reserved for patients who fail other surgical measures or who have intractable detrusor overactivity and desire a simplified method of management such as an abdominal urostomy. An ileovesicostomy (“chimney”) procedure or Bricker bilateral ureteroileostomy may be considered depending on the clinical circumstances including the presence or absence of native vesico-ureteral reflux (Leng, 1999) [412]. There are no studies that have examined these techniques in the treatment of non-neurogenic detrusor overactivity incontinence.

### **CONCLUSIONS**

Prospective, randomized, placebo (or sham) controlled trials of surgical therapy for detrusor overactivity incontinence are lacking. There is a need to critically assess these procedures in an evidenced based manner and compare them to each other as well as non-surgical therapies using a variety of outcome measures including quality of life parameters. (Table 8)

**Table 8. Enlargement Cystoplasty for Non-neurogenic Detrusor Overactivity Incontinence in Adult Women\***

Author	Year	No. patients*	mean age	bowel segment/Technique	Follow-up (mean)	success criteria	Cure rate	Success rate: Cue+improv	% on CIC	Level of evidence	Comments
<b>Enterocystoplasty</b>											
Bramble et al	1982	15 (7 female)	n/a	ileum or sigmoid	30 months	patient report: success=dry day and night	n/a	86.70%	13.3% (47.7% created to assist voiding)	Level 4	
Mundy et al	1985	40 (22 female)	28	ileum	12 months	patient report: cure=absence of presenting symptoms	90%	n/a	15%	Level 4	8 neuropathic patients included in the series
Kockelbergh et al	1991	45 (31 female)	45 (median)	ileum in 40 patients, colon in 5 patients	20.3 months	patient report: cure=absence of incontinence, improved= reduction in urgency	69%	71%	33% (54.8% with post-operative "voiding dysfunction")	Level 4	3 neuropathic patients included in the series
George et al	1991	31 (30 women)	51	ileum	48 months	patient report: cure=lack of symptomatic urge incontinence	74.20%	n/a		Level 4	2 IC and 1 radiation cystitis included
Hasan et al	1995	48 (31 women)	46	ileum in 46, colon in 2	38 months	unvalidated questionnaire and Viskick grading system Cure=patient report of voiding at will with no incontinence using an unvalidated questionnaire, improved= subjective improvement of symptoms	n/a	58%**	85%	Level 4	13 neuropathic patients included
Kelly et al	1997	27 (12 female)	41 (median)	ileum	18 months	cure= no pads by patient report, improved = "occasional leaks" or a mean of 1 pad per day	61%	72%	56%	Level 4	8 neuropathic patients included in the series
Awad et al	1998	51 (all female)	44.3	ileum	75.4 months		53%	78%	44%	Level 4	27 IC patients included in the series
<b>Detrusor Myectomy/Subareolar Myectomy</b>											
Kennelly et al	1994	5 (4 women)	41	detrusor myectomy	36.4 weeks	improved= improved compliance and bladder capacity	n/a	100%	100%	Level 4	3 neuropathic patients included and all patients had decreased compliance preoperatively
ter Meulen et al	1997	5 (3 women)	47	detrusor myotomy	3 months	n/a	n/a	20%	n/a	Level 4	4 neuropathic patients included
Swami, et al	1998	27 (n/a)	n/a	detrusor myectomy	27 months	Cure= patient report of lack of symptomatic urge incontinence, improved= patient report of improvement in urgency or urge incontinence	26%	63%	7.40%	Level 4	10 neuropathic patients included
Leng et al	1999	37 (n/a)	n/a	detrusor myectomy	n/a	improved= improved compliance on urodynamics	n/a	73%	n/a	Level 4	Series compared 32 enterocystoplasty cases to 37 detrusor myectomy cases

\*results reported for the entire cohort (males+females, and neurogenic+ non-neurogenic) unless otherwise noted

\*\*does not include neurogenic patients

n/a= not available, not applicable, or not reported

## Recommendations

**Augmentation enterocystoplasty should be reserved for patients who fail all forms of conservative therapy and are willing to accept the potential perioperative, and postoperative morbidity associated with the procedure as well as the potential need for permanent intermittent urethral catheterization. Women with non-neurogenic detrusor overactivity incontinence should be advised that, in the long term, only 50% of women are satisfied with the outcome from this procedure. (Grade C)**

## VI. COMPLICATIONS OF SURGERY FOR DETRUSOR OVERACTIVITY

### 1. AUGMENTATION CYSTOPLASTY

Complications associated with enterocystoplasty are significant and include those related to factors derived from the bowel segment being in direct contact with the urine as well as other operative and perioperative morbidity. Short and long term complications of enterocystoplasty have been recently reviewed by Greenwell et al and are summarized in **Table 9** [402]. Especially clinically relevant is the potential need for long-term clean intermittent catheterization in these patients. This possibility must be discussed with the patient preoperatively as patients should be willing and able to accept permanent clean intermittent catheterization (CIC) as a method of bladder emptying. Inability or unwillingness to perform CIC in those in

**Table 9. Complications related to enterocystoplasty \***

Complication	Reported Range (% of patients)
<b>Short Term Complications</b>	
Bleeding	0.75-3.2
Infection	1.5-9.0
Fistula	0-29.7
Small bowel obstruction	1.5-8.7
PE/DVT	1.1-7.1
MI	0-1.1
Patch necrosis	0-1.7
<b>Long Term Complications</b>	
CISC	14.0-100
Metabolic	0-19
Renal deterioration	0-56
Asymptomatic UTI	6.0-100
Symptomatic UTI	2.0-43
Stones	0-30
Perforation	0-9
Change in bowel habits	0-64
Failure to resolve underlying urinary problem	5.0-42

From Greenwell T.J., Venn S.N. and Mundv. A.R: Augmentationcystodasty. BJU International, 88: 511-525, 2001

whom it is necessary can lead to life threatening complications such as pouch perforation, urosepsis and death. Mucous build-up in the augmented bladder may also be troublesome but can be controlled by a number of measures [427]. Malignant transformation is a long-term risk of bladder augmentation and requires ongoing lifetime surveillance [428-430].

## VII. NEUROMODULATION

Sacral nerve stimulation (SNS) involves the stimulation of the sacral nerves to modulate the neural reflexes that influence the bladder, sphincter and pelvic floor. The initial experience with sacral nerve stimulation for use in bladder dysfunction was reported by Tanagho and Schmidt (1981) [431]. Since then, SNS using the Interstim (Medtronic, Minneapolis, Minnesota, U.S.A.) has been an invasive therapy that was approved by the FDA in 1997 for treatment of refractory urge incontinence. Use has been extended to include significant urgency, frequency and idiopathic urinary retention. World-wide, the number of implants passed 10,000 in 2003 with more than 70% of the implants in the U.S.

### a) Surgical Methods

Implantation of SNS consists of two steps: a) Stage I, or the trial stage – This involves the placement of a stimulation lead next to the dorsal root of S3 for a time period between 1-4 weeks. If the patient's symptoms under the existing list of indications for SNS improves more than 50 %, then the patient is a candidate to undergo the second step; b) Stage II or Permanent Step – In this step the permanent neurostimulator is implanted in the soft tissue of the buttock of the patient.

### b) Reports of RCT on three indications of UI, U/F and UR

The initial report on the efficacy of SNS on treatment of refractory urinary urge incontinence was reported in 1999 (Schmidt 1999) [432](Level 2- as no placebo or sham control was used). This study reported the treatment of 76 patients with refractory urgent urinary incontinence from 16 contributing worldwide centres. The patients were randomized to immediate implantation and a control group with delayed implantation for a six-month period. At six months, the number of daily incontinence episodes, severity of episodes, and absorbent pads or diapers replaced daily due to incontinence were significantly reduced in the stimulation group compared to the delayed group. Of the 34 stimulation group patients, 16 (47 percent) were completely dry, and an additional 10 (29 percent) demonstrated a greater than 50 percent reduction in incontinence episodes. The interesting finding was that during the therapy evaluation, the group returned to the baseline level of incontinence when the stimulation was inactivated. Complications



were site pain of the stimulator implantation in 16 percent, implants infection in 19 percent, and leak migration in 7 percent.

The use of SNS in urgency frequency was reported in 2000 (Hassouna 2000)<sup>433</sup>. Similar to the previous design, 51 patients from 12 centres were randomized into an immediate stimulation group and a control group (25 and 26 patients respectively) ((Level 2- as no placebo or sham control was used)). Patients were followed for one, three and six months, and afterwards at six-month intervals up to two years. At the six-month evaluation, the stimulation group showed improvement in the number of voiding episodes (16.9 + 9.7 to 9.3 + 5.1) volume per void (118 + 74 to 226 + 124 ml) and degree of urgency (the rank 2.2 + .6 to 1.6 + .9). In addition, significant improvement in quality of life was demonstrated, as measured by SF-36.

Use of SNS for urinary retention was published in 2001 (Jonas 2001)<sup>434</sup>, and in this study 177 patients with urinary retention refractory to conservative therapy were enrolled from 13 worldwide centres between 1993 and 1998 (Level 2- as no placebo or sham control was used). Thirty-seven patients were assigned to treatment and 31 to the control group. The follow-up was done at one, three, six, twelve and eighteen months. The treatment group showed 69 percent elimination of catheterization at six months and an additional 14 percent with a greater than 50 percent reduction in catheter volume per catheterization. Temporary inactivation of SNS therapy resulted in significant increase in residual volume, but the effectiveness of central nervous stimulation was sustained for 18 months after implantation.

In 2000, a follow-up report of some of these patients was published (Siegl 2000) [435] (Level 3). This report showed follow-up results after three years in all the indications. Fifty-nine percent of 41 had urinary urge incontinence. 46 percent of these patients were completely dry. After two years, 56 percent of the urgency frequency patients showed greater than 50 percent reduction in voids per day, and after 1-1/2 years, 70 percent of 42 retention patients showed greater than 50 percent reduction of catheter volume per catheterization.

The results of the use of SNS in the U.S. population were published in 2002 (Pettit 2000) [436] (Level 3). This publication showed the data collected from the U.S. patient registry. The report included the use of SNS in 81 patients with all three indications: 27 for urgent continence, 10 with urgency frequency and 10 with urinary retention. In this report, 27 from 43 patients with urgent continence, 10 out of 19 with urgency frequency and 10 out of 19 with urinary retention showed improvement of more than 50 percent.

The results of an Italian registry was published in

2001 (Spinelli 2001) [437] (Level 3). This report included the reports of 196 patients – 46 males and 150 females – for idiopathic urinary retention. 50 percent of patients stopped catheterization and another 13 percent catheterized once a day at one year after implantation. At the 12-month follow-up, 50 percent of patients with hyper-reflexia had less than one incontinence episode daily and the problem was completely solved in 66 patients. Of the patients with urgent continence, 39 percent were completely dry and 23 percent had less than one incontinence episode daily.

In Norway, the results of users of this modality were published in 2002 (Hedlund 2002) [438] (Level 3). The author reported the first three years of experience with 53 patients: 45 women and 8 men. This study showed similar results to previous studies.

### **c) Urinary Retention**

Aboseif et al 2002 reported on the use of SNS in functional urinary retention (Level 3). 32 patients were evaluated and underwent temporary PNE. Those who had a least a 50% improvement in symptoms during the test period underwent permanent generator placement. All patients who went to permanent generator placement were able to void spontaneously. There was both an increase in voided volume (48 to 198ml) and decrease in post void residual (315ml to 60 ml). 18/20 patients reported a greater than 50% improvement in quality of life.

### **d) Other Indications**

Use of SNS for other off-labelled applications has been reported in the form of abstracts. The off-labelled usage has included use of SNS in neurogenic bladder; interstitial cystitis, and chronic pelvic pain. All these results are limited case series reports. (Level 5)

### **e) Complications**

The reported complications of SNS includes infection, revision of stage I or II, lead migration, and undesirable stimulus. Changes in other visceral functions (sexual function; bowel function) has also been reported.

Stoller in 1987 reported that stimulation of the peripheral tibial nerve in pig-tailed monkeys was able to inhibit bladder overactivity (Gillon 1989) [439] (Level 3). This initial work led to its use in patients with refractory overactive bladder.

## **1. RESULTS**

In 2000 Klinger et al performed a prospective trial on 15 patients with urgency-frequency syndrome. They underwent 12 weeks of stimulation with the SANS device (Level 3). Ten patients responded with a reduction in voiding frequency per day (16 to 4) and daily leakage episodes (4 to 2.4). The only complication was one haematoma at the puncture site.

Govier et al (2001) [440° (Level 3) in a multicenter study reported the efficacy of SANS in 53 patients. All patients had refractory OAB and were seen at 5 different sites in the U.S. The patients completed a 12-week stimulation. 71% of the patients had at least a 25% decrease in daytime or night time frequency. No adverse effects were noted.

Level 2-3 evidence suggests that sacral neuromodulation may provide benefit in the treatment of patients with refractory urinary incontinence, urgency/frequency and idiopathic, non-obstructive urinary retention.

The mechanism of action of neuromodulation remains unknown.

The predictors of outcome and patient response to neuromodulation remain unknown.

Longer term and independent observational studies are needed to examine the longevity of the neuromodulation and identification of the most appropriate patient who should undergo this treatment.

## 2. COMPLICATIONS OF NEUROMODULATION

Several complications related to sacral neuromodulation have been well documented. Overall, the reported surgical revision or removal rate has been reported to be as high as 16-32% [441, 442]. Seigel et al reported on adverse events in 219 patients with pain at the stimulator site being the most common (Table 10) [443]. This is the most frequently reported complication in many series [442, 444]. Generally relocation of the device into another buttock or lower abdominal site will improve the pain.

**Table 10. Adverse events related to Interstim implantation in 219 patients\***

Pain at the stimulator site	15.3%
New pain	9.0%
Lead migration	8.4%
Infection	6.1%
Transient electric shock	5.5%
Pain at the lead site	5.4%
Changes in bowel function	3.0%

\*adapted from: [454]

Several recent studies have reported longer-term results of sacral neuro-modulation in a prospective fashion. van Kerrebroeck, et al reported a five-year prospective study using validated tools for urge incontinence, urinary frequency and retention<sup>445</sup>. 17 centres were included, worldwide, with 163 patients of whom 87% were female. Of these patients, 152 eventually underwent permanent implantation of the InterStim device. Of those undergoing implantation, 96 (63.2%) had urge incontinence and 25 (16.4%) had urgency and frequency. Voiding diaries were

collected post-insertion, annually, with clinical success being defined as 50% or greater improvement in primary voiding dysfunction variables. At five years, urge incontinence leaking episodes decreased from a mean of 9.6 (plus or minus 6) to 3.9 (plus or minus 4) episodes per day. For those patients with urinary urgency, mean voids decreased from 19.3, (plus or minus 7) per day to 14.8 (plus or minus 7.6) whereas mean voided volume increased from 92.3, (plus or minus 52.8 ) to 165.2 (plus or minus 147.7). All changes were noted to be statistically significant according to the authors' findings, with no life-threatening or irreversible adverse events being recorded. However, 279 device- or therapy -related adverse events in 102 patients were noted. Overall, 23.7% of patients during the study period required device exchange (36 patients). An additional twelve (7.9%) required re-positioning of the pulse generator, and ten (6.6%) required a lead and pulse generator replacement, and finally, ten (6.6%) required only lead re-positioning. An additional eleven patients (7.2%) required either permanent or temporary explantation, due to a variety of indications. The authors concluded that neuromodulation provided long-term benefit for urge incontinence, urinary frequency and urinary retention. (Level 3 evidence)

A second long-term outcomes report for neuro-modulation was published by van Voskuilen [446]. This was a single institution study and was a retrospective assessment of all patients implanted. There were 149 patients, including 107 subjects with urgency and frequency and/or urge incontinence as indication for implantation. Mean follow-up was 64.2 months (standard deviation 38.5). 194 adverse events were recorded, including six infections, with one explantation for infection. 129 re-operations were performed, with 21 complete explantations. There was a "learning curve" with time such that incidents of re-operations decreased substantially after 1996, correlating with improved experience with the device. This also correlated with a more "proactive" approach toward adverse events, including earlier diagnosis and intervention. Revision rates decreased overall from 4.25 in 1990, the first year of the study, to 0.00 from 2001 through the end of study, in 2003. The most common adverse event encountered in this population was pain with stimulation, followed by undesirable changes in voiding function, 64 and two, respectively, and pain at the IPG site, which was 41. There were also ten cases of lead migration and six cases of device-related failures.

Based upon a stringent review of the literature, a recent NICE guidance stated that sacral nerve stimulation was recommended for patients with detrusor overactivity who had failed conservative treatments. The NICE guideline concluded that approximately two-thirds of the patients achieved continence or at least substantial improvement of

symptoms over periods ranging from 3-5 years, with approximately one-third of the patients requiring a re-intervention due to device-site or infection related complications.

Barizzelli reported a systematic review of the literature and acknowledged a similar finding [447]

#### **Recommendation**

**Evidence Level: Sacral neuro-modulation appears to have benefit for patients with urge incontinence, as well as urgency and frequency. (Level 1, 2, and 3)**

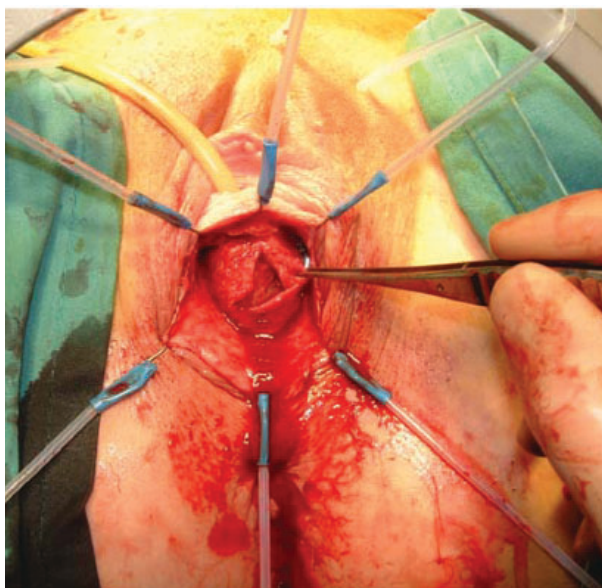
**Recommendation Level A.**

4 NICE guidelines reference

## **VIII. URETHRAL DIVERTICULUM**

Search of Medline for urethral diverticulum (UD) and female resulted in 576 published articles from 1952 to 2008. Despite case reports dating to 1786 (Hey), most studies consist of case series and consist of small numbers without control groups or comparison of differing interventions.

Diagnosis of UD was first advanced by Davis and Cian when they introduced the Double Balloon Positive Pressure Urethrography technique in 1956. Recently, longer term follow up studies post intervention and advances in imaging such as magnetic resonance imaging (MRI) has led to increased clinical awareness and diagnosis of this condition. (Daneshgari 1999) [448] (**Figure 12**).



**Figure 12 : Urethral diverticulum**

The important clinical topics concerning UD are:

- 1. CLASSIFICATION**
- 2. IMAGING MODALITY USED FOR CHARACTERIZATION AND DIAGNOSIS**
- 3. INDICATIONS FOR CONCOMITANT PROCEDURES SUCH AS ANTI-INCONTINENCE PROCEDURES,**
- 4. USE OF INTERPOSITIONING TISSUES.**
- 5. OUTCOME MEASURES AND COMPLICATIONS OF UD REPAIR**

#### **1. CLASSIFICATION**

Leach (Leach et al. 1993) [449] originated a classification system designed to accurately describe the characteristics of urethral diverticulae. The system utilizes the acronym LNSC3, which represents descriptive parameters for L = Location, N = Number, S = Size, C1 = Configuration, C2 = Communication, and C3 = Continence. In a series of 61 patients, urethral diverticulae were most commonly single in number (90 percent) and shape (62 percent). The location of the diverticulum swelling (62 percent), and ostium (60 percent) was mid-urethra. Fifty-six percent of the patients were incontinent (Leach et al 1993) [449].

Leng and McGuire divided diverticulae based on the integrity of the periurethral fascia, although diverticulae were described generally as primary diverticulae consisting of a mucosal layer only with narrow neck ostia bound by intact periurethral fascia. In contrast, pseudodiverticulae are often multi-layered with wide mouthed ostia on cystoscopic examination in association with a periurethral fascia defect. Rupture or erosion of the periurethral fascia often correlates with a history of prior suspension or a recurrent urethral diverticulae (Leng and McGuire 1998) [450]. These authors introduced the possibility that recurrence rates were influenced by global defects in the periurethral fascia thus potentiating de novo diverticulum formation or recurrence even after successful initial intervention.

#### **2. IMAGING MODALITY USED FOR CHARACTERIZATION AND DIAGNOSIS**

Optimal imaging modality for diagnosis of UD continues to be discussed in the literature. However, increasing data supports the definitive role of MRI examination in defining these lesions. The existing modalities include:

- a) Voiding Cysto Urethrogram (VCUG) /Double Balloon Retrograde Urethrography**
- b) Ultrasound**
- c) MRI**

The value of concomitant cystoscopy during the evaluation process lacks any significant evidence although this practice appears to be widely used.



Similarly, the use of urodynamics (with or without fluoroscopy) while very commonly done in naturalistic settings, has not been adequately studied to assess contribution to the overall assessment of UD.

#### **a) Voiding Cysto Urethrogram (VCUG) /Double Balloon Retrograde Urethrography**

In 1928, Norris and Kimbrough were the first to utilize cysto urethrography to define female bladder and urethral anatomy. A variation of this technique was repeated by Davis using a specialized double balloon catheter. Reported sensitivity for these techniques has ranged widely from 44 to 100 percent (Ganabathi 1994; Jacoby 1999; Golomb 2003 Level 3) [451-453]. Other authors have argued for the value of VCUG combined with urodynamics to assist in structural and functional analysis of the entire lower urinary tract. (Rufford, 2005, Level 4)[454]

#### **b) Ultrasound**

In 1977, Lee and Keller reported the use of abdominal ultrasound to identify urethral diverticulae (Lee 1977) [455] (Level 3). This modality may be used when a high clinical suspicion exists and when urethrographic results are negative. Diverticulae appear as anechoic or hypo echoic (to periurethral tissue) cavities with enhanced through transmission. Newer higher frequency ultrasound probes associated with intraluminal probe use may further enhance the utility of this technique. (Yang, 2004, Level 4) [456]. Ultrasound has been shown to have 100% sensitivity as compared to other modalities for the diagnosis of UD. (Gerrard, 2003, Level 3) [457].

#### **c) MRI (Figure 13)**

MRI has the advantage of multiplanar capabilities and excellent soft tissue definition. These qualities allow for differentiation between urethral diverticulae and other periurethral masses. Both T1 rated and T2 weighted images have been used or could be used for diagnosis of MRI. The T2 weighted images allow a high signal intensity of the urine, and collections within the urethral diverticulae making it a preferred method of imaging for urethral diverticulae (Level 3). The multiplanar capability of the MRI allows for a) identification of multiple urethral diverticulae; and, b) surgical planning for repair of the urethral diverticulae. Neitlich et al. applied a high-resolution fast stain echo MRI technique using a torso multicoil resulting in an examination time of 15 minutes. This study prospectively compared double balloon urethrography with MRI imaging of the urethra for detection of urethral diverticulae with a resultant sensitivity of 25 and 100 percent respectively. (Neitlich 1998 Level 2) [458] Another study evaluated diverticulae preoperatively with MRI classifying them simple, « U » shaped, or circumferential based upon MRI appearance. Recurrence after resection was significantly higher in « U » shaped (33%) or ring lesions (60%) then in



**Figure 13 : MRI picture illustrating a urethral diverticulum**

the simple group (0%).(Han, 2007, Level 2)459 MRI has also been shown to alter surgical management in some patients (15% of 27 patients). (Foster 2007, Level 4) [281]. Attempts at refining MRI technique using endo cavity techniques may improve detection and characterisation of these lesions. (Lorenzo, 2003, Level 3) [460].

There is no Level 1 evidence to support the optimal imaging modality. There are differences in the calculated sensitivity of each imaging modality between the various recorded studies. Moreover, the results of the studies are limited by differences in the patient population, study techniques, and interpretive skills of the radiologists.

### **3. TREATMENT**

Surgery for stress incontinence may be successfully performed along with urethral diverticulectomy. Leach (Leach and Bavendam 1987) [461] described simultaneous needle bladder neck suspension in 22 women with stress incontinence (Level 3). At the main follow-up of 20.5 months, 77 percent were totally continent and no significant complications were noted. Four of the five failures were secondary to ISD. Swierzewski (Swierzewski and McGuire 1993) [462] performed simultaneous autologous rectus fascia vaginal sling and urethral diverticulectomy in 14 women (Level 3). All were cured of the stress continence and one developed severe detrusor overactivity. The diverticulae recurred in one patient. More recent reports suggest that when an anti-incontinence procedure is not performed at time of diverticulectomy, rates of symptomatic incontinence are high with 49% of women reporting de novo SUI, and when incontinence was pre-existent, a 73% rate of persistence (Lee, 2008, Level 3) [485].

Use of labial (Martius) fat pad, vaginal wall bipediced



flap and autologous fascia in forms of pubovaginal sling has been used as interpositioning techniques for repair of UD. All reported cases are case series (Level 3). In several series, use of perivesical fascia as the interpositioning layer has been reported.

The optimal outcome of repair of UD is a) absence of UD recurrence; b) relief of symptoms; and c) absence of complications. A wide range of measured outcomes is reported in the literature mostly in form of case series (Level 3). The potential complications of the UD repair are reported as either short term (bleeding, urinary tract infection) or long term (urethrovaginal fistula, urethral pain syndrome, urinary incontinence, recurrent diverticulum). Recurrence of UD has been reported as long as 5 years after surgery. Presence or absence of additional pathologies such as neoplasm (squamous cell carcinoma, clear cell carcinoma, nephrogenic adenoma, vaginal leiomyoma), malakoplakia, and calculi formation within the UD has also been reported as an outcome measure. The incidence of concomitant pathology is reported in less than 5% of large series (Kochakarn 2000) [463].

In 1875, Tait was the first to report complete excision of a urethral diverticulae (Tait 1875) [464]. The following approaches have been reported in the literature for urethral diverticulum.

1. Endoscopic Approach – This technique uses a transurethral marsupialisation. (Davis 1970; Lapidus 1979) [465,466].
2. Packing/Obliterative Procedures – The diverticulae cavity is packed with oxidized cellulose followed by closure of the diverticulum and vaginal wall. (Ellik 1957) [467].
3. Open Marsupialisation – The Spence technique, which is essentially a meatotomy, is often performed for distal diverticulum connecting the posterior aspect of the urethral wall. (Spence 1970) [468].
4. Open Diverticulectomy – This technique uses mostly vaginal exposure to a) identify the diverticulum, b) dissect the diverticulum, c) repair the defect in the periurethral fascia. This technique has been the most widely used technique and the most widely reported in the literature. For the majority of the cases, a single closure of the periurethral fascia suffices for repair; however, use of additional inter-positioning tissues such as Martius fat pad has been reported.
5. Retropubic approach for ventrally based proximal diverticulae – This is used for very proximal and ventrally positioned proximal diverticulae, which are not the most common type of presentation for diverticulum.
6. Supra-Urethral meatus Approach to Ventrally Based Diverticulum – In this approach for urethrolysis, a semi-circle incision is made above the urethral

meatus thereby gaining an approach to the ventral urethral space.

7. Transvaginal resection with periurethral fascia dissection and layered closure (most common)
8. Urethral transection with circumferential dissection. (Rovner, 2003, Level 3) [469].

All the reported surgical techniques are case series (Level 3), and there is no published report of comparing the techniques or the outcomes in a prospective, randomized manner. One series reports the longest follow up of transvaginal resection. Sixty four women were followed up to twenty years, with recurrence in 11, urinary tract pain in 11, dyspareunia in 14, urinary urgency in 39 (12 with urge incontinence), and 24 with de novo stress incontinence. This report underscores the importance of assessing all functional outcomes of UD interventions. (Ljungqvist, 2007, Level 3) [470]

## IX. NON-OBSTETRIC URINARY FISTULAE

### I. INTRODUCTION

In developing countries birth trauma remains the aetiology for the majority of fistulae. (Arrowsmith 1996) [471]. In developed countries, modern obstetric care has substantially limited the risk of vesicovaginal fistulae and fistulae are usually the result of complications of gynaecological or other pelvic surgery. Evidence for fistula evaluation, timing of corrective intervention, methods of and adjuncts to correction, and associated management strategies is based on clinical series and / or case studies (Levels 2, 3 and 4) and lacks definitive randomized control analysis.

### 2. SPECIFIC AETIOLOGIES

In developed countries the most common cause of vesicovaginal fistula is routine abdominal or vaginal hysterectomy. At least 75% of genitourinary fistulae are subsequent to this cause (Jonas 1984, Symmonds 1984, Lee 1988, Tancer 1992) [472-475]. Fistulae occurring after hysterectomy are thought to be due to unrecognized direct bladder trauma, tissue necrosis caused by inadvertent suture placement through the bladder wall (probably most common and arising from suture placement at time of vaginal vault reconstruction), or thermal injury from electrocautery either as an isolated factor or in association with direct surgical injury. Tissue necrosis may also occur following previous surgery and with pelvic abscess or infection. Tissue necrosis results in fibrosis and induration, eventuating in an epithelial or mucosal lining of the fistula tract (Kursh, 1988) [476].

In 1980 Goodwin reported 32 patients with fistulae as a direct result of gynaecological intervention (Goodwin

1980) [477]. Tancer (1992) [475] noted a similar group of 151 patients and found that 91% (137) were postsurgical with 125 caused by gynaecological surgery. The most common procedure accounting for fistula was hysterectomy in 73% (110) of cases (99 of which were performed transabdominally). Factors thought to contribute to the risk of fistula formation due to hysterectomy include: prior caesarean section, intrinsic uterine disease (endometriosis) and prior ablative treatment for carcinomas (pelvic radiation therapy). Similar risk factors were identified by Blandy et al. (1991) [478]. The incidence of fistula after hysterectomy is generally accepted to be 0.1 - 0.2%. (Harris, 1995) [479] Recent meta- analysis of the gynaecological literature suggests that the rate of iatrogenic ureteral injury during hysterectomy approaches a crude occurrence rate of 6.2 per 1000 cases, while bladder injury occurs at 10.4 per 1000 cases. (Gilmour, 1999) [480] Additional surgical aetiologies include ; general surgical interventions in the pelvis (i.e. low anterior resection), anterior compartment repairs, or stress incontinence interventions. (Armenakas, Pareek, & Fracchia 2004) [481]. In a large series of 207 VVF, 83% were due to abdominal hysterectomy, 8% vaginal hysterectomy, 4 % radiation and the remainder miscellaneous causes (Eilber et al. 2003) [482]. Intraoperative cystoscopy appears to lessen the risk of fistula formation by up to 90% for ureteral and 85% for bladder lesions. (Gilmour, Dwyer, & Carey 1999) [480].

Other causes of fistulae include ; malignancy (Kottmeier, 1964) [483], radiation (Cushing, 1968 , Stockbine 1970, and Villasanta, 1972) [484-486] gastrointestinal surgery (low anterior resection) (Cross, 1993) [487], inflammatory bowel disease and urinary tuberculosis (Ba-Thike et al, 1992) [488]. Symmonds' experience at the Mayo clinic revealed only 5% of 800 vesicovaginal fistulae to be due to obstetric causes (Symmonds, 1984) [473]. Rarely, foreign bodies such as pessaries, diaphragms, and intrauterine devices also may lead to fistula formation (Goldstein et al, 1990) [489]. Iatrogenic CO2 laser therapy for cervical disease has also resulted in bladder fistulae (Colombel, 1995) [490]. Autoimmune diseases such as Behcet's have also been implicated as causative for vesicovaginal fistulae, due to extensive vasculitis related bladder wall necrosis. (Monteiro, 1995) [491]. Cervical, vaginal and endometrial carcinoma account for 3-5% of VVF in the developed world, and are the most common malignancies associated with this phenomenon.

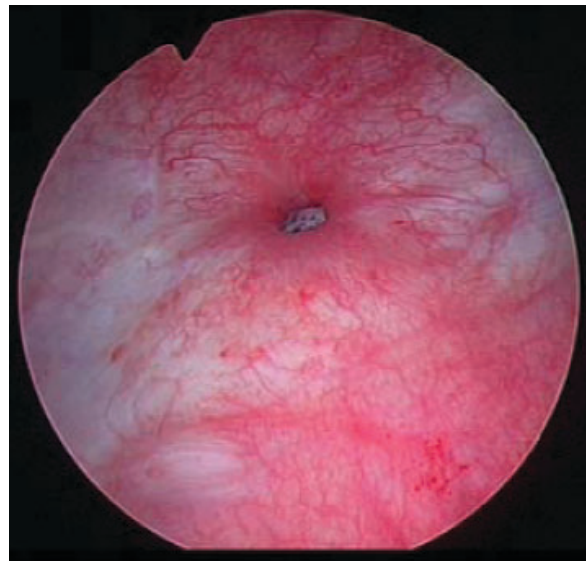
### 3. EVALUATION

The best preventative strategy for fistulas is early identification at the time of surgery with immediate repair of the bladder / ureteral injury. Physical examination is the most important diagnostic component in the evaluation of a woman with a suspected genitourinary fistula. Vaginal examination should try

to identify the fistula tract and the degree of vaginal access.

Aiding physical examination, dyes may be instilled into the bladder and coloured vaginal drainage assessed. This tool is particularly helpful for obscure fistulas (Drutz & Mainprize 1988) [492].

Cystoscopy (**Figure 14**) is a crucial adjunct to demonstrate the location and size of the fistula as well as proximity to one or both ureteral orifices. Cystoscopy also assesses the bladder mucosa for oedema and persistent necrosis which may complicate planned surgical repair.



**Figure 14 : Post-hysterectomy cystoscopic appearance of a VVF**

Patients may present while in the hospital with prolonged ileus, excessive pain, haematuria or flank pain (if a simultaneous ureteral injury also is present) (Kursh, 1998) [476]. If the fistula tract is large enough a significant amount, if not all, urine drains through the vagina, producing continuous or total incontinence. In other cases, fistula drainage may be minimal and intermittent and may be initially mistaken for stress incontinence occurring postoperatively. Patients with urethrovaginal fistulae arising from urethral catheter trauma may not develop symptoms until catheter removal has occurred. Incontinence arising from a urethrovaginal fistula may be intermittent unless the fistula extends across the bladder neck, in these cases severe and total incontinence is usually encountered. Fistulae may develop up to twenty years post radiation (Graham 1965; Raz 1992) [493,94]. Additionally, persistent clear vaginal discharge after hysterectomy may arise from leakage of peritoneal fluid from a vaginal cuff through a peritoneal sinus tract (posthysterectomy pseudo incontinence) (Ball, 1995) [494]. Ginsberg et al, 1998 [495], reported five patients with this finding, all of whom were cured by vaginal cuff revision.

Intravenous pyelography should be performed in women with any urinary fistula primarily to detect ureteric injury but also for congenital ureteric anomalies. Symmonds (1984) reported a 10% risk of a simultaneous ureteral component with vesicovaginal fistulae. The cystogram phase of the IVP may also suggest the presence of a fistula if early pooling of urine in the vagina occurs or wisps of urinary extravasation are noted. Retrograde pyelography may be employed for diagnosing the site of a ureterovaginal fistula or the possibility of a combined uretero- and vesicovaginal fistula, although no direct studies have evaluated this diagnostic technique against other imaging modalities.

Voiding cystourethrography (VCUG) may also help determine fistula presence and location. Also, the VCUG may demonstrate other lower urinary tract abnormalities that may impact upon surgical reconstruction (vesicoureteral reflux, cystocele, urethral diverticulum). Occasionally contrast examination of the vagina (vaginography) may help demonstrate an irregular fistulous tract. Zimmern et al (1994) [496] described the procedure for injecting contrast material through the vagina with a large balloon occluding the vaginal introitus. Level 3 evidence supports the use of this study.

Hilton (1998) [497] argues that urodynamics are necessary in the woman with a lower urinary tract fistula. He noted the following urodynamic abnormalities while evaluating 30 women with fistulae: 47% urodynamic stress incontinence, 44% detrusor overactivity, and 17% with poor bladder compliance. Urodynamics, however, are often difficult to perform due to continuous loss of instilled fluid through the fistula tract and therefore in many cases may not be additive to the overall evaluation of the patient. No evidence exists as to the role of urodynamics in predicting post-operative stress incontinence after fistula repair.

### **Summary**

The evaluation of urinary fistulae is based on evidence of loss of urine on physical evaluation, cystoscopic inspection of the bladder, and assessment of lower ureteral integrity (either IVP or retrograde pyelography).

Mandatory evaluation includes clinical examination with or without the use of dyes (Level 3) Intravenous urogram (Level 3,4),

Cystoscopy (Level 3)

Optional testing: Voiding cystourethrography (Level 3,4), Urodynamics (Level 4)

## **4. TREATMENT**

### **a) Conservative and minimally Invasive treatment**

Regardless of the timing of presentation, a trial of conservative therapy may be implemented which uses

continuous urethral catheter drainage. Level 4,5 evidence suggests that a variety of conservative techniques may be curative and possibly should be attempted first in patients with single fistula tracts which are less than 1 cm in size, and which are not associated with complicating factors such as prior radiation. Tancer et al (1992) [438] reported 3 of 151 patients with spontaneous closure of fistula using this strategy. Spontaneous closure occurred with 3 fistula tracts identified early in the postoperative period in 45 women managed in this fashion. Often, however, the patient has already undergone a trial of catheter drainage at the time of initial evaluation and therefore further catheter drainage may be helpful. No definitive evidence suggests the optimal time for catheter drainage. (Level 4)

Another possible conservative therapy utilizes electrocoagulation or fulguration of the lining of the fistulous tract (O'Connor 1980, Alonso 1985, Molina 1989, Stovsky, 1994) [498-501]. In Stovsky's experience 11 of 17 (73%) of patients with small (less than 3mm) fistulae treated with electrofulguration and 2 weeks of catheter drainage resolved. McKay (1997) [502] recently described successful cystoscopically placed suture closure of a vesicovaginal fistula, with no secondary incision.

Recently, the use of tissue adhesives has been described as a sealant for fistula tracts. Evans et al (2003) [503] reported the use of fibrin sealant for five patients who had complex vesicovaginal fistulae. All five were successfully managed without complication. (Level 4)

### **Summary**

Level 4/5 evidence suggests that conservative management techniques may be utilized in selected patients with small fistulae. More research is needed to better identify the patients who would best be managed in this manner.

### **b) Surgical Therapy**

#### **1. TIMING OF INTERVENTION**

Previously, many authors have advocated a waiting period of at least 3 to 6 months before intervening with surgical therapy (O'Connor 1951, Wein 1980, Blandy 1991) [504,505,478]. No specific evidence exists as to the need for this delay in intervention. More recently surgeons have advocated an individualized approach without an observational period. Several authors have reported excellent results with early interventions (Persky, 1979, Goodwin 1980, Wang 1990, Raz 1992, Blaivas 1995, Raz 2000) [506,477,507,94,508,509]. There is Level 3 evidence that fistulae identified within the first 24 to 48 hours postoperatively can be safely repaired immediately. Those identified days to weeks after surgery require careful planning and selection. Wang and Hadley



successfully managed 15 of 16 (94%) high lying (vaginal apical) fistulae through a transvaginal approach, with all 7 patients who were less than three months from initial surgery cured of fistula. (Wang 1990) [507].

### **Summary**

The timing for surgical intervention may depend on presenting factors such as tissue integrity. Intervention immediately following early diagnosis is successful in some series. Additionally, surgical approach (abdominal versus vaginal may also impact this decision). More research is necessary to identify optimal timing of fistula repair.

Evidence for timing of Surgery Level 4,5

## **2. PREOPERATIVE PREPARATION**

No specific evidence supports any preoperative preparation as being crucial for surgical success. Individualization of operative decision will be impacted by the unique needs of each woman undergoing intervention. Local preparation such as vaginal douches with antiseptic agents the evening before and the morning of surgery have been used in the past but no evidence supports this technique. A recent RCT evaluating the use of antibiotic prophylaxis for fistula surgery showed no benefit to use of perioperative antibiotics (Tomlinson AJ & Thornton JG 1998) [510]. Oestrogen replacement therapy has also been used in those patients with poor quality of vaginal tissues (Raz 1992) [94]. (Level 4/5)

### **Summary**

No specific preoperative preparation has been shown to alter outcome. Antibiotic prophylaxis does not influence post-operative infective morbidity or outcome. (Level 1 / 2)

## **3. SURGICAL APPROACHES**

Surgical approaches used for vesicovaginal fistulae include: combined abdominal vaginal, vaginal, or abdominal approaches. The approach chosen is dependent upon several factors, including location of fistula, quality of the tissues, and surgical experience and training. Vaginal surgery is more rapid and results in less morbidity and more rapid recovery; however, the vaginal route is difficult in patients with a significant degree of fibrosis, pelvic immobility, or with large fistula tracts with possible injury in close proximity to the ureteral orifices. (Carr & Webster 1997) [329] (Dupont & Raz 1996) [511] The abdominal approach may be more appropriate for the poorly visualized tract, the narrow or immobile vagina, and those with close proximity to a ureteral orifice. Laparoscopic repair also provides an alternative approach.

Other considerations for surgical repair include; type of suture, method of urinary drainage, and the use of tissue interposition graft.

There is only level 4 and 5 evidence to support any of the surgical techniques.

## **5. VAGINAL APPROACH**

The vaginal approach utilizes an anterior vaginal wall flap for coverage. Subsequently a tension free closure is performed utilizing a long acting (polyglycolic acid or polydioxanone) suture and non-overlapping multiple closure lines. Interposition tissue may be mobilized from labia, peritoneum, or vagina.

There is only level 4,5 evidence to support these techniques.

A suprapubic catheter should be placed (Zeidman 1988) [512]. Urinary drainage may also be supplemented with a urethral catheter. If the fistula communication occurs in proximity to the ureteral orifices, ureteric catheterization with cystoscopic assistance is generally performed prior to fistula closure. Optimal visualization is dependent on tissue mobility. The use of lateral relaxing incisions may help operative visualization and approach to the fistulous tract (Zimmern 1994) [602]. If the fistula repair is tenuous or there is concern regarding apposition of suture lines a Martius interpositional graft may be utilized. If this is not obtainable, alternative graft sources include a peritoneal flap (Raz 1993) [513] or an interposition graft utilizing gracilis muscle tissue. The peritoneum can be freed from the posterior aspect of the bladder and easily advanced to cover the layers of the closure as well (Raz 1993) [513]. (Level 4)

Level 4,5 evidence suggests that the Martius labial interposition graft provides a satisfactory graft material (Raz 1992, Blaivas 1995, Blaivas 2000, Hoskins, 1984) [94,508,514,515]. Several authors have used this graft as an adjunct to repair associated with complicated incontinence with excellent results. (Ghoniem 1995, Carr 1997) [517,329] Martius flap interposition has been used for both urethrovaginal and vesicovaginal fistulas and seemed to convey an advantage (0 recurrences in 13 women) over repairs which did not use flap interposition (4 recurrences in 21 women) (Rangnekar, Imdad, Kaul, & Pathak 2000) [518].

The vast majority of vesicovaginal fistulae can be closed in one operation using the previously described approach. Raz reported a success rate of 92% (64/69) for vesicovaginal fistulae, 2/3 of which had failed 1 to 3 prior repairs using this technique (Raz 1992) [94]. Many of these repairs used a peritoneal graft interposition.

Other variants for vaginal the approach include the Latzko which essentially produces a partial colpocleisis with risks of vaginal shortening and overlapping suture lines. (Enzelsberger & Gitsch 1991) [519] Additionally, vaginal cuff excision has been advocated as another ablative method for closing fistula tracts. (Iselin, Aslan,



& Webster 1998; Flynn, Peterson, Amundsen, & Webster 2004) [520,521].

Eilber et al recently reported a 10 year experience with interposition graft use in 120 patients undergoing vaginal repair of fistula. In 83 a peritoneal graft was used, in another 34 a Martius graft was interposed, and in 3 a labial interposition was applied. The success rates were 96, 97, and 33% respectively. (Level 3) No intraoperative complications were reported.

## **6. ABDOMINAL APPROACH**

All bladder fistulae (except those extending into the urethra) may be approached utilizing the abdominal approach, and this is the preferred approach in those patients requiring bladder augmentation or ureteral re-implantation. The earliest experience was reported by O'Connor (1951, 1973) for abdominal transvesical repair of vesicovaginal fistulae. This technique may require placement of ureteral catheters to localize the ureteral orifices. An abdominal incision is then performed (midline or pfannenstiel), followed by bisection of the bladder to the level of fistula. The bladder and vagina are mobilized and separated from each other by dissecting along the vesicovaginal septum. A complete excision of the fistula tract is completed. If the tract is extensively indurated, a posterior bladder flap may be mobilized to repair the defect. (Gil-Vernet, 1989) [522]. Recently, Nesrallah et al reported a 100% success rate using the O'Connor transabdominal supratrigonal technique in 29 patients. (Nesrallah 1999) [523]. Other authors have reported similar results.

Separate closure of the vagina and bladder are performed utilizing absorbable sutures (polydioxanone or polyglycolic) and may be performed intra - or extraperitoneally. The intraperitoneal technique allows for easy harvest of the omentum.

Level 4 evidence supports the use of omentum as an interpositional graft. Wein (1980b) [524] utilizing an omentum graft based on the right gastroepiploic artery noted adequate length and tension free apposition of this tissue between the vaginal and vesical components of the fistula repair. Other authors have found the omentum to be reproducibly present for interpositional uses. (Turner-Warwick, 1976) [525] (Kiricuta, 1972) [526] The omentum is secured between the bladder and vagina with 3-0 polyglycolic acid sutures.

Bladder augmentation can also be performed with the intraperitoneal approach into the already bivalved bladder. Large or small bowel may be utilized. This closure is often reinforced with an omentum pedicle graft. Reported success rates with this approach are approximately 85% - 90% and have been reported by numerous authors. (Marshall 1979, Wein 1980a, Gil-Vernet 1989, Udeh 1985, Demirel 1993, Kristensen 1994, Blaivas 1995, Raz 2000) [527,505,522,528-530,508].

## **7. LAPAROSCOPIC APPROACH**

Laparoscopy provides an alternative approach for fistula repair. Level 3,4 evidence suggests that this approach may be successful for some patients. Nehzat et al (1994) [531] reported a successful repair of a laparoscopically caused fistula in a single patient. In a larger series Ou et al (2004) [543] evaluated retrospectively the value of laparoscopic repair as compared to vaginal or abdominal repair in 16 patients. Only two patients actually underwent laparoscopic repair, and both repairs were successful, however one patient had a prolonged hospitalization. (Level 5 Evidence)

## **8. COMPLICATED VESICOVAGINAL FISTULAE**

Complicated vesicovaginal fistulae can be defined as those fistulae of large size (3 to 5 centimetres or greater in diameter), fistulae occurring after prior attempt at closure, fistulae associated with prior radiation therapy, fistulae associated with malignancy, fistulae occurring in compromised operative fields due to poor healing or host characteristics, and fistulae that involve the trigone, bladder neck and/or urethra

Several Level 4/5 studies report results for complicated fistulae. Reconstructive techniques have been described utilizing a variety of interpositional tissues including fibrofatty labial interposition tissues, anterior/posterior bladder flaps (autografts), myocutaneous flaps including rectus, sartorius, gluteus, and gracilis muscle flaps as well as combined myocutaneous flaps (Garlock 1928, Byron 1969, Stirnemann 1969, Menchaca 1990, Blaivas 1991, Raz 1992, Candiani 1993, Tancer 1993, Brandt 1998) [532-534,94,535-539] as adjuncts to repair of the complex vesicovaginal fistula (Patil 1980, Bissada, 1992) [540,541] (Level 4 / 5 Evidence)

Prior radiation therapy may increase the risk of vesicovaginal fistula despite the use of the tissue interposition (Obrink 1978, Raz 1992) [542,94]. Overall results range around 50% successful closure, but Bissada achieved 80% successful closure in his group of 10 post-radiation patients. (Bissada, 1992 Level 5 Evidence) [541]

### **Summary**

No specific intra-operative intervention has been shown to influence outcome.

Urethrovaginal fistulae may be very small pinpoint fistulae demonstrated by vaginal voiding or may present as complete urethral and bladder neck loss with total urinary incontinence. This circumstance most commonly results from prior gynaecological surgery, with anterior repair and urethral diverticulectomy comprising the most common inciting procedures (Blaivas 1989, Raz 2000) [555,520] (Level 4 Evidence)

Previously, birth trauma was a cause of majority of urethral defects; however, in developed nations this is now a rare cause of urethrovaginal fistulae. Prolonged obstructive labour, however, remains a major cause of urethral injury in developing nations (Elkins 1994) [544].

Level 4 Evidence suggests that techniques used for urethrovaginal fistula closure are very similar to those utilized for transvaginal vesicovaginal fistula repair (Webster 1984) [545]. A significant difference however is that the urethrovaginal fistula should not be completely excised but rather circumscribed and oversewn. Complete urethral loss is a more daunting surgical challenge and a multiplicity of techniques has been described for this (Blaivas 1989, Blaivas 1996, Hendren 1980 and 1998, Patil 1980) [555,546-548,540]. These techniques usually employ some type of flap utilizing either vaginal, bladder, or alternative tissue in an inlay versus tabularised reconstruction (Blaivas 1989) [555]. Simultaneous stress incontinence procedures should be performed to obviate the risk of postoperative incontinence (Blaivas 1990) [549] (Level 3,4 Evidence)

#### ***i) Preoperative Evaluation***

The physical examination is important to identify the extent and amount of urethral loss and associated vaginal pathologies such as prolapse and functional problems such as stress incontinence.

#### ***ii) Operative Technique***

Small to intermediate size fistulae may be managed with a tension-free layered closure. Distal fistulae may be managed with extended meatotomy (Spence 1970) [468]. (Level 5) Complete reconstruction is necessary for large fistulae with extensive loss including those that involve the bladder neck. The optimal continence procedure required in such cases has not been critically studied.

Interpositional tissue should be considered whenever the closure lines or vaginal tissues are of poorer quality (Webster 1984, Leach 1991) [545,550] (Level 4,5 Evidence)

#### ***Summary***

Although the risk of non-obstetric fistulae after gynaecological surgery approaches 0.1% in developed countries, evidence supporting optimal surgical preparation, approach and technique, and post surgical management is predominantly based on case series (Level 4).

Conservative or minimally invasive management (including catheter drainage, cystoscopic fulguration of fistula tract, and use of occlusive agents) has been reported the overall results for vesicovaginal fistulae with these methods are highly variable. Expert opinion suggests that an attempt at conservative management

should be considered during the early management of a newly diagnosed vesicovaginal fistula. (Level 4 / 5)

Although vaginal, abdominal, and laparoscopic techniques have been described no clear advantage exists between these techniques. Very little evidence supports laparoscopic management. Surgeon preference, fistula location, and complicating factors (such as prior pelvic radiation, altered wound healing – i.e. chronic steroid use, proximity to ureteral orifices, and time of diagnosis) may all impact on method of repair. Timing of repair (Level 4) appears not to influence long term success and surgical repair may be performed at time of identification if factors such as wound healing are considered optimal by the operative surgeon.

Evidence supporting surgical adjuncts such as use and type of interpositional tissues and effect on outcome of repair is limited (Level 4).

## **X. OUTCOME MEASURES**

Rigorous scientific assessment of the outcome of surgery for urinary incontinence is important because it enables comparison to be drawn between procedures. Patients can then make informed decisions in light of the risks and benefits demonstrated. Health care providers can identify cost effective treatments and surgeons can bench mark their practice.

Commonly used outcome measures are urodynamics, pad tests, bladder diaries, symptom questionnaires, symptom-bother questionnaires, quality of life (QoL) instruments, and measures of satisfaction. All of these tools are discussed in more detail by other chapters. The aim of this section is to highlight issues specific to the assessment of surgical outcome.

Any outcome measure must be reliable, valid, and responsive to change. It is also important that the results are interpretable within clinical practice.

Reliability concerns the extent to which an experiment, test or any measurement yields the same results on repeated trials.

Any measurement will have a degree of error associated with it. If this is large the test is not reliable and it is unlikely to be a useful outcome measure.

### **1. OBJECTIVE TESTS**

#### ***a) Urodynamics***

Several studies have demonstrated that urodynamics have poor test re-test reliability. Homma et al (Homma et al. 2000) [606] demonstrated that on repeating urodynamics after 2-4 weeks the results tend towards

normality. There was a 10-13% increase in bladder volumes ( $p < 0.01$ ), a 10% decrease in the number of subjects with detrusor overactivity and 18% reduction in the amplitude of detrusor contractions.

The test-retest reliability of urodynamics to detect detrusor overactivity was investigated in children by Griffiths et al. Urodynamics were repeated on three occasions, 10% changed from stable to unstable and 14% from unstable to stable (Griffiths et al. 1982) [551].

Cardozo et al. found 15% of women who complained of stress incontinence had no demonstrable loss on videourodynamics but were wet on Urilos pad tests (Cardozo et al. 1980) [552]. Urodynamics appeared not to be sensitive enough to detect this loss.

In 1997, Jensen et al. reviewed 26 studies that compared the urodynamic diagnosis to patients' symptoms. They found that urodynamic evaluation failed to demonstrate incontinence in up to 25% (mean 9%) of patients who complained of urinary leakage (Jensen et al. 1997) [553].

Studies comparing static to ambulatory urodynamics have shown 25-60% of patients, with symptoms of overactive bladder, have negative stationary tests for detrusor overactivity which can then be identified on ambulatory testing (van Waalwijkvan Doorn et al. 1987; Griffiths et al. 1989; Webb et al. 1991) [554, 580, 557]. However there is no test re-test data for ambulatory studies.

Hilton demonstrated that post operative urodynamics failed to demonstrate leakage in almost 40% of women who on questionnaire responses still had some leakage.

Post-operatively urodynamics have become the gold standard in the 'objective' assessment of surgical outcome (Jarvis 1994) [20]. However, there is little evidence of reliability to support this position.

### **b) Cough stress test**

This can be a useful test to assess the resolution of stress incontinence following surgery (Yalcin et al. 2004) [558]. It however cannot be used to assess improvement. Before and after surgery the test should be standardised for bladder volume, number and force of coughs, and the position of the subject. There is no agreed standard for these factors and this limits the use of cough test data in meta-analysis of incontinence surgery.

### **c) Pad tests**

Pad tests have been used to objectively define cure using a cut-off point at which the test is positive. There is considerable variation in the duration of pad tests are used. Short pad test 1-hour have been demonstrated to be unreliable measures and therefore not suitable outcome measures (Simons et al. 2001) [559].

There is evidence that the 72 hour pad test is most reliable duration for pad testing (Karantanis et al. 2005) [560].

The number of pads used per 24 hours has been shown not to accurately reflect the amount of urine lost. (Dylewski et al. 2007) [561].

However all of these evaluations have been made in pre treatment samples and therefore may not be valid post-operatively when leakage episodes may be less frequent and severe.

### **d) Bladder Diaries**

Bladder diaries, 3- 7 days, have been shown to be reliable measures of incontinence prior to surgery (Wyman et al. 1988) [562] however, their reliability may also be a function of the duration of the test and the frequency of incontinence episodes. Hence following surgery a patient with infrequent but bothersome incontinence episodes may appear cured on a 3 day diary- having no incontinence episodes. There has been no research to establish the clinical significance of improvements in bladder diaries, whether change in incontinence episodes should be reported as a percentage change from baseline or in reduction in the number of episodes.

## **2. SYMPTOM QUESTIONNAIRES**

There are several symptom questionnaires available. Committee X has evaluated the psychometric properties of the available symptom questionnaires in detail, using an A,B,C grading system.

The content of a questionnaire is a psychometric property which is important, yet frequently overlooked. In selecting a symptom questionnaire for a surgical study it is important to consider if the instrument covers the recognised complications. For example the Severity of Symptoms Index SSI is a psychometrically valid instrument but it only addresses stress incontinence symptoms (Black et al. 1996) [237]. It does not measure common complications such as voiding difficulty or overactive bladder. Few questionnaires have comprehensive assessment of the impact incontinence on sexual function.

If an instrument is being used to assess a new innovation then one should select an instrument with the capacity to report in free text other symptoms not covered by the questionnaire.

Other factors which should be considered are the incidence of recurrent UTI, any pad use, drugs for OAB, re-operation, clean intermittent self catheterisation rates, and the speed of recovery. These can be used to compare procedures and are useful to counsel patients before surgery.

Another property to consider is does the questionnaire measure the presence of symptoms and the bothersomeness as separate items? Some instru-

ments separate symptoms and bother e.g. BFLUTS however others combine these factors one question e.g. KHQ.

Bother is a complex factor which is probably affected by personality, previous experience, other comorbidities and other factors. It is probably therefore more useful to use separate questions of symptoms and bother.

Symptoms are easily comparable between studies for meta analysis however they cannot be summated into a meaningful primary end point.

New innovations can be associated with new complications. It is important that these are assessed. Although it is difficult to compare the significance of different complications.

### 3. QUALITY OF LIFE (QoL) INSTRUMENTS

Committee x has provide a comprehensive review of the large number of QoL instruments available and their psychometric properties, reliability, validity, responsiveness.

To be a useful outcome measure in research & clinical practice the output of these instruments must have clinical meaning. Many studies report statistic changes in score but these have no clinical meaning. Further research is required to establish clinical meaning.

The most commonly use method to establish this is Minimally Clinically Important Change (MCID), although even this has limitations. There are several method to calculate MCID and it is probably disease and population dependant (Wyrwich et al. 2005) [563]. To date three QoL instruments have reported MCID but none are for a surgical interventions (Kelleher et al. 2004; Yalcin et al. 2006; Hendriks et al. 2008) [564-566]. MCID is not specific to an instrument and therefore for should currently be calculated for each study.

QoL instruments frequently are divided into domains for example physical, social, emotional & personal. An individual may attribute different importance to each of these domains therefore they should not be combined into a global score unless there is psychometric evidence that this is valid. Instead a global assessment scale should be used.

### 4. GLOBAL ASSESSMENT SCALES

This is term applied to a health-related index that provides a broad overview of a complex phenomenon. Selection of a response involves a patient implicitly evaluating feelings, perceptions, opinions, expectations, goal achievement, satisfaction, beliefs, and previous health state and then coming to a single judgement.

Global assessments usually consist of a single question. There are two common formats; state evaluation (How are you today?) and transition evaluations (How are you compared to before treatment?).

These scales are very simple to use and are clinically intuitively understandable however they lack detail to identify reason for success or failure.

They are often used as anchor questions to determine MCID of QoL instruments.

The fact that a global impression index results in a single score means they can used as primary endpoints.

### 5. SATISFACTION

Almost 30 years ago, Norton hypothesised that a reduction in the number of leaks by 50% may not mean patients feel 50% better (Norton 1982) [567]. It may be that the fact of being incontinent, regardless of the amount or frequency, is what determines restrictions. This implies that nothing short of total dryness will be accepted by the patient as success.

It is this concept which is addressed when assessing satisfaction.

Satisfaction is also a function of patients' goals and expectations.

Robinson et al found that 43% patients wanted " a good improvement so that symptoms no longer interfere with their life" however 17 % expected a complete cure of all symptoms in keeping with the National Institute of Health (NIH) definition of cure. The NIH definition of cure of stress incontinence is the resolution of the symptom of incontinence, the resolution of the sign of stress incontinence (a negative stress test with a full bladder) and the absence of new symptoms or side effects (Weber et al. 2001) [568].

It may be that pre-operative counselling can alter patients' expectations and thereby ultimately alter the outcome of surgery – if it is assessed through satisfaction.

### 6. HEALTH-ECONOMIC OUTCOMES

Several incontinence operations appear to have similar efficacy. The trend is to develop less invasive operations for incontinence. Health-economic factors may ultimately be the only significantly different factor between procedures. Generic instruments such as ED-5D from which QALYs can be estimated may not be sensitive enough to detect change however there are currently no condition specific tools available. A preference-based measure of health developed from the King's Health Questionnaire has been published however this is for use in OAB conditions not stress incontinence. (Brazier et al. 2008) [569]

### CONCLUSION

Currently used objective outcome measures may not be sensitive enough to detect surgical failure. The only 'subjective' outcome measure which does not involve complex judgemental factors is the assessment of symptoms. These should be administered using a validated symptom questionnaire, by an independent party to avoid bias associated with patient surgeon



relationship. Symptoms are easily comparable between studies for meta analysis however because they consist of multiple answers they are not suitable as primary outcome measure. The lack clinical meaning of results from QoL instruments restricts their usefulness and requires further research. In view of this a validated global impression scale may be a better primary outcome measure. Until further research establishes a universal outcome tool it is advisable to use multiple outcomes. This is in keeping with the recommendation of several societies and regulatory organisations; the AUA (Lose et al. 1998) [261], the NIH (Weber et al. 2001) [568] the IUGA, (Ghoniem et al. 2008) [570] and ICS (Mattiasson et al. 1998) [571].

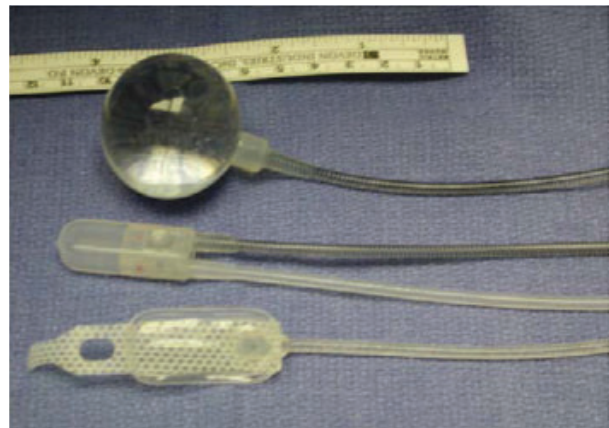
### Recommendations

1. Most outcome measures used have been developed in non-surgical areas. Further research is required ensure they are clinically useful surgical outcome measures.
  - a. When a QoL instrument is to be used ensure the study includes a calculation of MCID.
  - b. A validated global impression index may be a useful primary outcome measure for surgical trials.
2. Until further research establishes a universal outcome tool it is advisable to use multiple outcomes.
  - a. Symptoms and separate bother questionnaire
  - b. Clinical important outcomes (pad use, re-operation rates, anticholinergics, CISC, recurrent UTI)
  - c. Complications
  - d. QoL tool with MCID
  - e. Global Impression Index
  - f. Health- economic outcome

## XI. ARTIFICIAL URINARY SPHINCTER IN WOMEN

The artificial urinary sphincter has been utilized for the treatment of sphincter dysfunction in women in special circumstances (failed prior procedures) or rarely as a primary intervention. The majority of experience with the artificial urinary sphincter in women has been in neurogenic patients, with comparatively little data for women with non-neurogenic stress incontinence. The procedure may be performed either by a transvaginal [572] or transabdominal approach [573,574] (**Figure 15**).

Appell in 1988 reported results of artificial sphincter implantation in 34 women who experienced complete



**Figure 15 : Components of the AUS**

continence, with only three of the 34 requiring revision after transvaginal placement [575] Subsequently, Hadley in 1991 reported 13 of 14 patients (93%) who attained reasonable urinary control (defined as no or one pad per day for stress incontinence).

Various authors have proposed either the trans-abdominal or the transvaginal approach as being superior due to operative technique-related issues, including operative dissection for cuff placement though no robust evidence is available to support their views. The trans-vaginal approach is considered to be superior for cuff dissection and placement. The transabdominal approach is considered to provide better exposure, especially for bladder neck placement, assuring placement between the urethra and the vaginal wall [573,576,577]. Laparoscopic placement has been described as a method to decrease morbidity associated with the abdominal approach [578].

Overall success rates range between 76% and 89%, with lower success rates and higher revision rates being noted in those patients with neurogenic voiding dysfunction as the primary indication for placement. The most extensive experience with artificial sphincter implantation is that of Costa (2001) who reported 207 patients with a mean of four-year follow-up. An overall success rate of 89% was reported in the non-neurogenic population with an overall vaginal extrusion rate of 6%.

A recent Cochrane Review failed to find sufficient evidence to support use of the artificial urinary sphincter and recommended large scale clinical trials to determine the possible role of these devices in the management of incontinence in women [579].

### Recommendation

Only Level 3 / 4 evidence is available to support use of the artificial sphincter. This would support a Level B recommendation for use.

## REFERENCES

- 1 HILTON, P. (2008) Long-term follow-up studies in pelvic floor dysfunction: the Holy Grail or a realistic aim? *BJOG*, 115, 135-43.
- 2 BLACK, N. A. & DOWNS, S. H. (1996) The effectiveness of surgery for stress incontinence in women: a systematic review. *Br J Urol*, 78, 497-510.
- 3 DOWNS, S. & BLACK, N. (1996) Systematic review of the literature on the effectiveness of surgery for stress incontinence in women. Department of Public Health & Policy Publications. London, Health Services Research Unit, London School of Hygiene & Tropical Medicine.
- 4 ATKINS, D. et al (2004) Systems for grading the quality of evidence and the strength of recommendations I: critical appraisal of existing approaches The GRADE Working Group. *BMC Health Services Research*, 4, 38.
- 5 ATKINS, D. et al (2004) Grading quality of evidence and strength of recommendations. *BMJ*, 328, 1490.
- 6 ATKINS, D., et al. (2005) Systems for grading the quality of evidence and the strength of recommendations II: pilot study of a new system. *BMC Health Services Research*, 5, 25.
- 7 GUYATT, G. H., et al. (2008) GRADE: What is "quality of evidence" and why is it important to clinicians? *BMJ*, 336, 995-998.
- 8 GUYATT, G. H. et al, (2008) GRADE: going from evidence to recommendations. *BMJ*, 336, 1049-1051
- 9 GUYATT, G. H., et al: (2008) GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*, 336, 924-926.
- 10 MATTIASSON, A., PETERS, T. I., SCHAFER, W., BLAIVAS, J. G., JONAS, U., STANTON, S. & LOSE, G. (1999) Research methodology in incontinence. IN ABRAMS, P., KHOURY, S. & WEIN, A. (Eds.) *Incontinence: WHO - UICC International Consultation on Incontinence – 1st edition*. Plymouth, UK, Health Publication Ltd.
- 11 MOEHRER, B., ELLIS, G., CAREY, M. & WILSON, P. D. (2000) Laparoscopic colposuspension for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD002239. DOI: 10.1002/14651858.CD002239.
- 12 BEZERRA, C. A., BRUSCHINI, H. & CODY, D. J. (2001) Suburethral sling operations for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD001754. DOI: 10.1002/14651858.CD001754.
- 13 GLAZENER, C. M. A. & COOPER, K. (2001) Anterior vaginal repair for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 1. Art. No.: CD001755. DOI: 10.1002/14651858.CD001755.
- 14 PICKARD, R., REAPER, J., WYNESS, L., CODY, D. J., MCCLINTON, S. & N'DOW, J. (2003) Periurethral injection therapy for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD003881. DOI: 10.1002/14651858.CD003881.
- 15 GLAZENER, C. M. A. & COOPER, K. (2004) Bladder neck needle suspension for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD003636. DOI: 10.1002/14651858.CD003636.pub2.
- 16 BEZERRA, C. A., BRUSCHINI, H. & CODY, D. J. (2005) Traditional suburethral sling operations for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD001754. DOI: 10.1002/14651858.CD001754.pub2
- 17 LAPITAN, M. C., CODY, D. J. & GRANT, A. M. (2005) Open retropubic colposuspension for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD002912. DOI: 10.1002/1465 1858. CD002912.pub2.
- 18 DEAN, N. M., ELLIS, G., WILSON, P. D. & HERBISON, G. P. (2006) Laparoscopic colposuspension for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD002239. DOI: 10.1002/14651858.CD002239.pub2.
- 19 KEEGAN, P. E., ATIEMO, K., CODY, J., MCCLINTON, S. & PICKARD, R. (2007) Periurethral injection therapy for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD003881. DOI: 10.1002/14651858.CD003881.pub2. .
- 20 JARVIS, G. J. (1994) Surgery for genuine stress incontinence. *British Journal of Obstetrics & Gynaecology*, 101, 371-374.
- 21 ARVIS, G., BENT, A., CORTESE, A., MCGUIRE, E., MILANI, R., QUARTEY, J., RICHARD, F., SMITH, A., ZIMMERN, P. & GHONEIM, J. (1999) Surgical treatment for incontinence in adult women - Surgery of female lower genito-urinary fistulae. IN ABRAMS, P., KHOURY, S. & WEIN, A. (Eds.) *Incontinence: WHO - UICC International Consultation on Incontinence – 1st edition*. Plymouth, UK, Health Publications Ltd.
- 22 SMITH, A., DANESHGARI, F., DMOCHOWSKI, R., GHONEIM, G., JARVIS, G., NITTI, V. & PARAISO, M. F. (2002) Surgery for urinary incontinence in women. IN ABRAMS, P., CARDOZO, L., KHOURY, S. & WEIN, A. (Eds.) *Incontinence: WHO - ICUD International Consultation on Incontinence – 2nd edition*. Plymouth, UK, Health Publications Ltd.
- 23 SMITH, A., DANESHGARI, F., DMOCHOWSKI, R., MILANI, R., MILLER, K., PARAISO, M. F. & ROVNER, E. (2005) Surgery for urinary incontinence in women. IN ABRAMS, P., CARDOZO, L., KHOURY, S. & WEIN, A. (Eds.) *Incontinence: WHO - ICUD International Consultation on Incontinence – 3rd edition*. Plymouth, UK, Health Publications Ltd.
- 24 LEACH, G. E., DMOCHOWSKI, R. R., APPELL, R. A., BLAIVAS, J. G., HADLEY, H. R., LUBER, K. M., MOSTWIN, J. L., O'DONNELL, P. D. & ROEHRBORN, C. G. (1997) Female Stress Urinary Incontinence Clinical Guidelines Panel summary report on surgical management of female stress urinary incontinence. *The American Urological Association. Journal of Urology*, 158, 875-880.
- 25 QUADRI, G., SCALAMBRINO, S., BOISIO, N., MARCHESIN, R. & MILANI, R. (1985) Randomized surgery for incontinence and prolapse: Retropubic colposuspension vs anterior repair. *Archives of Gynecology & Obstetrics*.
- 26 STANTON, S. L., CHAMBERLAIN, G. & HOLMES, D. M. (1985) Randomised study of the anterior repair and colposuspension operation in the control of genuine stress incontinence. *International Continence Society, 15th annual meeting*. London
- 27 KLARSKOV, P., BELVING, D., BISCHOFF, N., DORPH, S., GERSTENBERG, T., OKHOLM, B., PEDERSEN, P. H., TIKJOB, G., WORMSLEV, M. & HALD, T. (1986) Pelvic floor exercise versus surgery for female urinary stress incontinence. *Urologia Internationalis*, 41, 129-32
- 28 BERGMAN, A., BALLARD, C. A. & KOONINGS, P. P. (1989) Comparison of three different surgical procedures for genuine stress incontinence: Prospective randomized study. *American Journal of Obstetrics & Gynecology*, 160, 1102-1106.
- 29 BERGMAN, A., KOONINGS, P. P. & BALLARD, C. A. (1989) Primary stress urinary incontinence and pelvic relaxation: Prospective randomized comparison of three different operations. *American Journal of Obstetrics & Gynecology*, 161, 97-101.
- 30 BERGMAN, A. & ELIA, G. (1995) Three surgical procedures for genuine stress incontinence: Five-year follow-up of a prospective randomized study. *American Journal of Obstetrics & Gynecology*, 173, 66-71.
- 31 BERGLUND, A. L. & LALOS, O. (1996) The pre- and postsurgical nursing of women with stress incontinence. *Journal of Advanced Nursing*, 23, 502-511.
- 32 LIAPIS, A., PYRGIOTIS, E., KONTORAVDIS, A., LOURIDAS, C. & ZOURLAS, P. A. (1996) Genuine stress incontinence: prospective randomized comparison of two operative methods. *European Journal of Obstetrics, Gynecology, & Reproductive Biology*, 64, 69-72.
- 33 LIAPIS, A. E., ASIMIADIS, V., LOGHIS, C. D., PYRGIOTIS, E. & ZOURLAS, P. A. (1996) A randomized prospective study of three operative methods for genuine stress incontinence. *Journal of Gynecologic Surgery*, 12, 7-14.
- 34 BERGLUND, A. L., EISEMANN, M., LALOS, A. & LALOS, O. (1997) Predictive factors of the outcome of primary surgical treatment of stress incontinence in women. *Scandinavian Journal of Urology & Nephrology*, 31, 49-55.
- 35 KAMMERER-DOAK, D. N., DORIN, M. H., ROGERS, R. G. & COUSIN, M. O. (1999) A randomized trial of burch retropubic urethropexy and anterior colporrhaphy for stress urinary incontinence. *Obstetrics & Gynecology*, 93, 75-78.

- 36 LUTKE, J. J., KLUTKE, C. G., BERGMAN, J. & ELIA, G. (1999) Bladder neck suspension for stress urinary incontinence: how does it work? *Neurourology & Urodynamics*, 18, 623-7.
- 37 COLOMBO, M., VITOBELLO, D., PROIETTI, F. & MILANI, R. (2000) Randomised comparison of Burch colposuspension versus anterior colporrhaphy in women with stress urinary incontinence and anterior vaginal wall prolapse. *BJOG: An International Journal of Obstetrics & Gynaecology*, 107, 544-551.
- 38 LALOS, O., BERGLUND, A. L. & BJERLE, P. (2000) The long-term outcome of retropubic urethrocytostomy (sutures and fibrin sealant) and pubococcygeal repair. *Acta Obstetrica et Gynecologica Scandinavica*, 79, 135-139.
- 39 DI PALUMBO, V. S. (2003) Four-corner bladder and urethral retropubic suspension versus anterior colporrhaphy in the correction of stress urinary incontinence with urethrocytostoele 3-4. Randomized clinical trial. *Urogynaecologia International Journal*, 17, 57-68.
- 40 MESCHIA, M., FIFAROTTI, P., SPENNACCHIO, M., BUONAGUIDI, A., GATTEI, U. & SOMIGLIANA, E. (2004) A randomized comparison of tension-free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence. *American Journal of Obstetrics & Gynecology*, 190, 609-613.
- 41 BURCH, J. (1961) Urethrovaginal fixation to Cooper's ligament for stress incontinence, cystocele and prolapse. *American Journal of Obstetrics & Gynecology*, 81, 281-290.
- 42 BURCH, J. C. (1968) Cooper's ligament urethrovesical suspension for stress incontinence. Nine years' experience—results, complications, technique. *American Journal of Obstetrics & Gynecology*, 100, 764-774.
- 43 CAREY, M. P., GOH, J. T., ROSAMILIA, A., CORNISH, A., GORDON, I., HAWTHORNE, G., MAHER, C. F., DWYER, P. L., MORAN, P. & GILMOUR, D. T. (2006) Laparoscopic versus open Burch colposuspension: a randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*, 113, 999-1006.
- 44 DUMVILLE, J. C., MANCA, A., KITCHENER, H. C., SMITH, A. R., NELSON, L., TORGERSON, D. J. & ON BEHALF OF THE COLPO STUDY GROUP (2006) Cost-effectiveness analysis of open colposuspension versus laparoscopic colposuspension in the treatment of urodynamic stress incontinence. *BJOG: An International Journal of Obstetrics & Gynaecology*, 113, 1014-1022.
- 45 WARD, K. L., HILTON, P. & ON BEHALF OF THE UK & IRELAND TVT TRIAL GROUP (2008) Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. *BJOG: An International Journal of Obstetrics & Gynaecology*, 115, 226-233.
- 46 ALBO, M. E., et al, and Urinary Incontinence Treatment Network (2007) Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *New England Journal of Medicine*, 356, 2143-2155.
- 47 SIVASLIOGLU, A. A., CALISKAN, E., DOLEN, I. & HABERAL, A. (2007) A randomized comparison of transobturator tape and Burch colposuspension in the treatment of female stress urinary incontinence. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 18, 1015-1019.
- 48 COLOMBO, M., SCALAMBRINO, S., MAGGIONI, A. & MILANI, R. (1994) Burch colposuspension versus modified Marshall-Marchetti-Krantz urethropexy for primary genuine stress urinary incontinence: A prospective, randomized clinical trial. *American Journal of Obstetrics & Gynecology*, 171, 1573-1579.
- 49 QUADRI, G., MAGATTI, F., BELLONI, C., BARISANI, D. & NATALE, N. (1999) Marshall-Marchetti-Krantz urethropexy and Burch colposuspension for stress urinary incontinence in women with low pressure and hypermobility of the urethra: early results of a prospective randomized clinical trial. *American Journal of Obstetrics & Gynecology*, 181, 12-18.
- 50 MCCRERY, R. J. & THOMPSON, P. K. (2005) Outcomes of urethropexy added to paravaginal defect repair: A randomized trial of Burch versus Marshall-Marchetti-Krantz. *Journal of Pelvic Medicine and Surgery*, 11, 137-143.
- 51 MUNDY, A. R. (1983) A trial comparing the Stamey bladder neck suspension procedure with colposuspension for the treatment of stress incontinence. *British Journal of Urology*, 55, 687-690.
- 52 GERMAN, K. A., KYNASTON, H., WEIGHT, S. & STEPHENSON, T. P. (1994) A prospective randomized trial comparing a modified needle suspension procedure with the vagina/obturator shelf procedure for genuine stress incontinence. *British Journal of Urology*, 74, 188-190.
- 53 ATHANASSOPOULOS, A. & BARBALIAS, G. (1996) Burch colposuspension versus Stamey endoscopic bladder neck suspension: a urodynamic appraisal. *Urologia Internationalis*, 56, 23-27.
- 54 GILJA, I., PUSKAR, D., MAZURAN, B. & RADEJ, M. (1998) Comparative analysis of bladder neck suspension using Raz, Burch and transvaginal Burch procedures. A 3-year randomized prospective study. *European Urology*, 33, 298-302.
- 55 COLOMBO, M., MILANI, R., VITOBELLO, D. & MAGGIONI, A. (1996) A randomized comparison of Burch colposuspension and abdominal paravaginal defect repair for female stress urinary incontinence. *American Journal of Obstetrics & Gynecology*, 175, 78-84.
- 56 ENZELSBERGER, H., HELMER, H. & SCHATTEIN, C. (1996) Comparison of Burch and Iyodura sling procedures for repair of unsuccessful incontinence surgery. *Obstetrics & Gynecology*, 88, 251-256.
- 57 SAND, P. K., WINKLER, H., BLACKHURST, D. W. & CULLIGAN, P. J. (2000) A prospective randomized study comparing modified Burch retropubic urethropexy and suburethral sling for treatment of genuine stress incontinence with low-pressure urethra. *American Journal of Obstetrics & Gynecology*, 182, 30-34.
- 58 DEMIRCI, F. & YUCEL, O. (2001) Comparison of pubovaginal sling and burch colposuspension procedures in type I/II genuine stress incontinence. *Archives of Gynecology & Obstetrics*, 265, 190-194.
- 59 CULLIGAN, P. J., GOLDBERG, R. P. & SAND, P. K. (2003) A randomized controlled trial comparing a modified Burch procedure and a suburethral sling: long-term follow-up. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 14, 229-233.
- 60 BAI, S. W., SOHN, W. H., CHUNG, D. J., PARK, J. H. & KIM, S. K. (2005) Comparison of the efficacy of Burch colposuspension, pubovaginal sling, and tension-free vaginal tape for stress urinary incontinence. *International Journal of Gynecology & Obstetrics*, 91, 246-251.
- 61 TENNSTEDT, S. & Urinary Incontinence Treatment Network (2005) Design of the Stress Incontinence Surgical Treatment Efficacy Trial (SISTER). *Urology*, 66, 1213-1217.
- 62 MALLETT, V. T., BRUBAKER, L., STODDARD, A. M., BORELLO-FRANCE, D., TENNSTEDT, S., HALL, L., HAMMONTREE, L. & URINARY INCONTINENCE TREATMENT, N. (2008) The expectations of patients who undergo surgery for stress incontinence. *American Journal of Obstetrics & Gynecology*, 198, 308. e1-6.
- 63 RICHTER, H. E., DIOKNO, A., KENTON, K., NORTON, P., ALBO, M., KRAUS, S., MOALLI, P., CHAI, T. C., ZIMMERN, P., LITMAN, H., TENNSTEDT, S. & URINARY INCONTINENCE TREATMENT NETWORK (2008) Predictors of treatment failure 24 months after surgery for stress urinary incontinence. *Journal of Urology*, 179, 1024-1030.
- 64 LIAPIS, A., BAKAS, P. & CREATSAS, G. (2002) Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women. *European Urology*, 41, 469-473.
- 65 WARD, K. L., HILTON, P. & ON BEHALF OF THE UK & IRELAND TVT TRIAL GROUP (2002) Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. *BMJ*, 325, 67-70.
- 66 WANG, A. C. & CHEN, M. C. (2003) Comparison of tension-free vaginal taping versus modified Burch colposuspension on urethral obstruction: a randomized controlled trial. *Neurourology & Urodynamics*, 22, 185-190.
- 67 WARD, K. L., HILTON, P. & ON BEHALF OF THE UK & IRELAND TVT TRIAL GROUP (2004) A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence:



- two-year follow-up. *American Journal of Obstetrics & Gynecology*, 190, 324-331.
- 68 EL-BARKY, E., EL-SHAZLY, A., EL-WAHAB, O. A., KEHINDE, E. O., AL-HUNAYAN, A. & AL-AWADI, K. A. (2005) Tension free vaginal tape versus Burch colposuspension for treatment of female stress urinary incontinence. *International Urology & Nephrology*, 37, 277-281.
  - 69 SU, T. H., WANG, K. G., HSU, C. Y., WEI, H. J. & HONG, B. K. (1997) Prospective comparison of laparoscopic and traditional colposuspensions in the treatment of genuine stress incontinence. *Acta Obstetrica et Gynecologica Scandinavica*, 76, 576-582.
  - 70 FATTHY, H., EL HAO, M., SAMAHA, I. & ABDALLAH, K. (2001) Modified Burch colposuspension: laparoscopy versus laparotomy. *Journal of the American Association of Gynecologic Laparoscopists*, 8, 99-106.
  - 71 CHEON, W. C., MAK, J. H., LIU, J. Y., MAK, J. H. L. & LIU, J. Y. S. (2003) Prospective randomised controlled trial comparing laparoscopic and open colposuspension. *Hong Kong Medical Journal*, 9, 10-14.
  - 72 ANKARDAL, M., MILSOM, I., STJERNDAHL, J. H. & ENGH, M. E. (2005) A three-armed randomized trial comparing open Burch colposuspension using sutures with laparoscopic colposuspension using sutures and laparoscopic colposuspension using mesh and staples in women with stress urinary incontinence. *Acta Obstetrica et Gynecologica Scandinavica*, 84, 773-779.
  - 73 USTUN, Y., ENGIN-USTUN, Y., GUNGOR, M. & TEZCAN, S. (2005) Randomized comparison of Burch urethropexy procedures concomitant with gynecologic operations. *Gynecologic & Obstetric Investigation*, 59, 19-23
  - 74 KITCHENER, H. C., DUNN, G., LAWTON, V., REID, F., NELSON, L., SMITH, A. R. & GROUP, O. B. O. T. C. S. (2006) Laparoscopic versus open colposuspension—results of a prospective randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*, 113, 1007-1013.
  - 75 DIETZ, H. P. & WILSON, P. D. (2005) Laparoscopic colposuspension versus urethropexy: a case-control series. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 16, 15-18.
  - 76 MCCracken, G. R., HENDERSON, N. A. & ASHE, R. G. (2007) Five year follow-up comparing tension-free vaginal tape and colposuspension. *Ulster Medical Journal*, 76, 146-149.
  - 77 SUN, M. J., NG, S. C., TSUI, K. P., CHANG, N. E., LIN, K. C. & CHEN, G. D. (2006) Are there any predictors for failed Burch colposuspension? *Taiwanese Journal of Obstetrics & Gynecology*, 45, 33-38.
  - 78 NG, S., TEE, Y. T., TSUI, K. P. & CHEN, G. D. (2007) Is the role of Burch colposuspension fading away in this epoch for treating female urinary incontinence? *International Urogynecology Journal & Pelvic Floor Dysfunction*, 18, 937-942
  - 79 RARDIN, C. R., SUNG, V. W., HAMPTON, B. S., CLEMONS, J. L., AGUILAR, V. & SOKOL, E. R. (2007) Long-term follow-up of a transvaginal Burch urethropexy for stress urinary incontinence. *American Journal of Obstetrics & Gynecology*, 197, 656.e1-656.e5.
  - 80 MAHER, C. F., DWYER, P. L., CAREY, M. P. & MORAN, P. A. (1999) Colposuspension or sling for low urethral pressure stress incontinence? *International Urogynecology Journal*, 10, 384-9.
  - 81 BIDMEAD, J., TOOZS-HOBSON, P., CARDOZO, L., ROBINSON, D. & BAILEY, J. (2001) Randomised comparison of Burch colposuspension versus anterior colporrhaphy for patients with stress urinary incontinence (letter). *BJOG: An International Journal of Obstetrics & Gynaecology*, 108, 128-129.
  - 82 ALCALAY, M., MONGA, A. & STANTON, S. L. (1995) Burch colposuspension: a 10-20 year follow up. *British Journal of Obstetrics & Gynaecology*, 102, 740-745.
  - 83 THAKAR, R., STANTON, S., PRODICALIDAD, L. & DEN BOON, J. (2002) Secondary colposuspension: results of a prospective study from a tertiary referral centre.[see comment]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 109, 1115-1120.
  - 84 HENRIKSSON, L. & ULMSTEN, U. (1978) A urodynamic evaluation of the effects of abdominal urethrocystopexy and vaginal sling urethroplasty in women with stress incontinence. *American Journal of Obstetrics & Gynecology*, 131, 77-82.
  - 85 MCDUFFIE, R. W., LITIN, R. B. & BLUNDON, K. E. (1981) Urethrovesical suspension (Marshall-Marchetti-Krantz). Experience with 204 cases. *American Journal of Surgery*, 141, 297-298.
  - 86 COLOMBO, M., VITOBELLO, D., PROIETTI, F., ARREGHINI, A. & PASTA, F. (1998) Results and complications of the modified Marshall-Marchetti-Krantz procedure. *Italian Journal of Gynaecology & Obstetrics*, 10, 91-96.
  - 87 CZAPLICKI, M., DOBRONSKI, P., TORZ, C. & BORKOWSKI, A. (1998) Long-term subjective results of Marshall-Marchetti-Krantz procedure. *European Urology*, 34, 118-123.
  - 88 LUNA, M. T., HIRAKAWA, T., KAMURA, T., YAHATA, H., OGAWA, S., SONODA, T. & NAKANO, H. (1999) Comparison of the anterior colporrhaphy procedure and the Marshall-Marchetti-Krantz operation in the treatment of stress urinary incontinence among women. *Journal of Obstetrics & Gynaecology Research*, 25, 255-260.
  - 89 HEGARTY, P. K., POWER, P. C., O'BRIEN, M. F. & BREDIN, H. C. (2001) Longevity of the Marshall-Marchetti-Krantz procedure. *Annales Chirurgiae et Gynaecologiae*, 90, 286-289.90
  - 90 DEMIRCI, F., YILDIRIM, U., DEMIRCI, E., AYAS, S., ARIOGLU, P. & KUYUMCUOGLU, U. (2002) Ten-year results of Marshall Marchetti Krantz and anterior colporrhaphy procedures. *Australian & New Zealand Journal of Obstetrics & Gynaecology*, 42, 513-514.
  - 91 PEREYRA, A. J. (1959) A simplified surgical procedure for the correction of stress incontinence in women. *Western Journal of Surgery, Obstetrics & Gynecology*, 67, 223-226.
  - 92 STAMEY, T. A. (1973) Endoscopic suspension of the vesical neck for urinary incontinence. *Surgery, Gynecology & Obstetrics*, 136, 547-554.
  - 93 GITTES, R. F. & LOUGHLIN, K. R. (1987) No-incision pubovaginal suspension for stress incontinence. *Journal of Urology*, 138, 568-570.
  - 94 RAZ, S., SUSSMAN, E. M., ERICKSON, D. B., BREGG, K. J., NITTI, V. W. & BLAIVAS, J. G. (1992) The Raz bladder neck suspension: Results in 206 patients. *Journal of Urology*, 148, 845-850.
  - 95 PALMA, P. C., SOFFIATTI, S. A., ALMEIDA, S. C. & PINOTTI, J. A. (1988) Stress urinary incontinence: a comparative study of surgical treatment by the Marshall-Marchetti-Krantz technique with endoscopic suspension of the bladder neck. Second report. *Asia Oceania J Obstet Gynaecol*, 14, 31-6.
  - 96 HILTON, P. (1989) A clinical and urodynamic study comparison the Stamey bladder neck suspension and suburethral sling procedures in the treatment of genuine stress incontinence. *British Journal of Obstetrics & Gynaecology*, 96, 213-220.
  - 97 STEIN, M. & WEINBERG, J. J. (1991) Polytetrafluoroethylene vs. polypropylene suture for endoscopic bladder neck suspension. *Urology*, 38, 119-122.
  - 98 HILTON, P. & MAYNE, C. J. (1991) The Stamey endoscopic bladder neck suspension: A clinical and urodynamic investigation, including actuarial follow-up over four years. *British Journal of Obstetrics & Gynaecology*, 98, 1141-1149.
  - 99 REID, S. V. & PARYS, B. T. (2005) Long-term 5-year followup of the results of the vesica procedure. *Journal of Urology*, 173, 1234-1236
  - 100 TROCKMAN, B. A., LEACH, G. E., HAMILTON, J., SAKAMOTO, M., SANTIAGO, L. & ZIMMERN, P. E. (1995) Modified Pereyra bladder neck suspension: 10-year mean followup using outcomes analysis in 125 patients. *Journal of Urology*, 154, 1841-1847.



- 101 MILLS, R., PERSAD, R. & HANDLEY ASHKEN, M. (1996) Long-term follow-up results with the Stamey operation for stress incontinence of urine. [see comment]. *British Journal of Urology*, 77, 86-8.
- 102 GOLDBERG, R. P., TCHETGEN, M. B., SAND, P. K., KODURI, S., RACKLEY, R., APPELL, R. & CULLIGAN, P. J. (2004) Incidence of pubic osteomyelitis after bladder neck suspension using bone anchors. [see comment]. *Urology*, 63, 704-708.
- 103 GREGORAKIS, A., BOUROPOULOS, C., DIMITRIOU, D., RALLIS, G., VERNADAKIS, S., PAPADOPOULOS, I. N. & KASTRIOTIS, I. (2006) Delayed reaction to the Dacron buttress used in Stamey bladder neck suspension. *International Urology & Nephrology*, 38, 269-272.
- 104 SMITH, A. & ROVNER, E. (2006) Long-term chronic complications from Stamey endoscopic bladder neck suspension: a case series. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 17, 290-294.
- 105 WHITE, G. R. (1909) Cystocele: a radical cure by suturing lateral sulci of vagina to the white line of pelvic fascia. *Journal of the American Medical Association*, 53, 1707-1709.
- 106 WHITE, G. R. (1912) An anatomical operation for the cure of cystocele. *American Journal of Diseases of Women*, 65, 286-288.
- 107 RICHARDSON, A. C., LYON, J. B. & WILLIAMS, N. L. (1976) A new look at pelvic relaxation. *American Journal of Obstetrics & Gynecology*, 126, 568-573.
- 108 RICHARDSON, P. (1997) Re: The intravaginal slingplasty operation, a minimally invasive technique for cure of urinary incontinence in the female (1) [see comment] [comment]. *Australian & New Zealand Journal of Obstetrics & Gynaecology*, 37, 485.
- 109 SCOTTI, R. J., GARELY, A. D., GREYTON, W. M., FLORA, R. F. & OLSON, T. R. (1998) Paravaginal repair of lateral vaginal wall defects by fixation to the ischial periosteum and obturator membrane. *American Journal of Obstetrics & Gynecology*, 179, 1436-1445.
- 110 BRUCE, R. G., EL-GALLEY, R. E. S. & GALLOWAY, N. T. M. (1999) Paravaginal defect repair in the treatment of female stress urinary incontinence and cystocele. *Urology*, 54, 647-651.
- 111 OSTRZENSKI, A. (1998) Genuine stress urinary incontinence in women. New laparoscopic paravaginal reconstruction. *Journal of Reproductive Medicine*, 43, 477-82.
- 112 MIKLOS, J. R. & KOHLI, N. (2000) Laparoscopic paravaginal repair plus burch colposuspension: review and descriptive technique. *Urology*, 56, 64-69.
- 113 MALLIPEDDI, P. K., STEELE, A. C., KOHLI, N. & KARRAM, M. M. (2001) Anatomic and functional outcome of vaginal paravaginal repair in the correction of anterior vaginal wall prolapse. *International Urogynecology Journal*, 12, 83-8.
- 114 CLEMONS, J. L., MYERS, D. L., AGUILAR, V. C. & ARYA, L. A. (2003) Vaginal paravaginal repair with an AlloDerm graft. *American Journal of Obstetrics & Gynecology*, 189, 1612-1618.
- 115 BURTON, G. (1999) A five year prospective randomised urodynamic study comparing open and laparoscopic colposuspension. *Neurourology & Urodynamics*, 18, 295-296 (abstract).
- 116 SUMMITT, R., LUCENTE, V., KARRAM, M., SHULL, B. & BENT, A. (2000) Randomised comparison of laparoscopic and transabdominal Burch urethropexy for the treatment of genuine stress incontinence. *Obstetrics & Gynecology*, 94, 2 (abstract).
- 117 MORRIS, A., REILLY, E., HASSAN, A., RAMSAY, I. & HAWTHORN, R. (2001) 5-7 year follow-up of a randomised trial comparing laparoscopic colposuspension (LC) and open colposuspension (OC) in the treatment of genuine stress incontinence. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 12, s6 (abstract).
- 118 ANKARDAL, M., EKERYDH, A., CRAFOORD, K., MILSOM, I., STJERNDAHL, J. H. & ENGH, M. E. (2004) A randomised trial comparing open Burch colposuspension using sutures with laparoscopic colposuspension using mesh and staples in women with stress urinary incontinence. *BJOG: An International Journal of Obstetrics & Gynaecology*, 111, 974-981.
- 119 PERSSON, J., BOSSMAR, T. & WOLNER-HANSEN, P. (2000) Laparoscopic colposuspension: a short term urodynamic follow-up and a three-year questionnaire-study. *Acta Obstetrica et Gynecologica Scandinavica*, 79, 414-20.
- 120 USTUN, Y., ENGIN-USTUN, Y., GUNGOR, M. & TEZCAN, S. (2003) Tension-free vaginal tape compared with laparoscopic Burch urethropexy. *Journal of the American Association of Gynecologic Laparoscopists*, 10, 386-389 [erratum appears in *J Am Assoc Gynecol Laparosc*. 2003 Nov;10(4):581].
- 121 MAHER, C., QATAWNEH, A., BAESSLER, K., CROPPER, M. & SCHLUTER, P. (2004) Laparoscopic colposuspension or tension-free vaginal tape for recurrent stress urinary incontinence and/or urethral sphincter deficiency - a randomised controlled trial. *Neurourology & Urodynamics*, 23, 433-434 (abstract).
- 122 PARAISO, M. F., WALTERS, M. D., KARRAM, M. M. & BARBER, M. D. (2004) Laparoscopic Burch colposuspension versus tension-free vaginal tape: a randomized trial. *Obstetrics & Gynecology*, 104, 1249-1258.
- 123 VALPAS, A., KIVELA, A., PENTTINEN, J., KUJANSUU, E., HAARALA, M. & NILSSON, C. G. (2004) Tension-free vaginal tape and laparoscopic mesh colposuspension for stress urinary incontinence. *Obstetrics & Gynecology*, 104, 42-49.
- 124 MIROSH, M. & EPP, A. (2005) TVT vs laparoscopic Burch colposuspension for the treatment of stress urinary incontinence. *International Continence Society, 35th annual meeting*. Montreal, Canada.
- 125 PERSSON, J. & WOLNER-HANSEN, P. (2000) Laparoscopic Burch colposuspension for stress urinary incontinence: a randomized comparison of one or two sutures on each side of the urethra. *Obstetrics & Gynecology*, 95, 151-155.
- 126 ROSS, J. (1996) Two techniques of laparoscopic Burch repair for stress incontinence: a prospective, randomized study. *Journal of the American Association of Gynecologic Laparoscopists*, 3, 351-357.
- 127 ZULLO, F., PALOMBA, S., PICCIONE, F., MORELLI, M., ARDUINO, B. & MASTRANTONIO, P. (2001) Laparoscopic Burch colposuspension: a randomized controlled trial comparing two transperitoneal surgical techniques. *Obstetrics & Gynecology*, 98, 783-788.
- 128 WALLWIENER, D., GRISCHKE, E., RIMBACH, S., MALEIKA, A. & BASTERT, G. (1995) Endoscopic retropubic colposuspension: "Retziusscopy" versus laparoscopy - a reasonable enlargement of the operative spectrum in the management of recurrent stress incontinence? *Endoscopic Surgery & Allied Technologies*, 3, 115-118.
- 129 DEAN, N. M., HERBISON, P., ELLIS, G. & WILSON, D. (2006) Laparoscopic colposuspension and tension-free vaginal tape: a systematic review. *BJOG: An International Journal of Obstetrics & Gynaecology*, 113, 1345-1353.
- 130 TAN, E., TEKKIS, P. P., CORNISH, J., TEOH, T. G., DARZI, A. W. & KHULLAR, V. (2007) Laparoscopic versus open colposuspension for urodynamic stress incontinence. *Neurourology & Urodynamics*, 26, 158-169.
- 131 PICCIONE, F., ZULLO, F., PALOMBA, S., SENA, T., GIOVINAZZI, F., BIAMONTE, M., LEONARDI, I. & MASTRANTONIO, P. (2001) Different techniques of laparoscopic Burch colposuspension. *Italian Journal of Gynaecology & Obstetrics*, 13, 10-13.
- 132 JELOVSEK, J. E., BARBER, M. D., KARRAM, M. M., WALTERS, M. D. & PARAISO, M. F. R. (2008) Randomised trial of laparoscopic Burch colposuspension versus tension-free vaginal tape: long-term follow up. *BJOG: An International Journal of Obstetrics & Gynaecology*, 115, 219-225.
- 133 VALPAS, A., RISSANEN, P., KUJANSUU, E. & NILSSON, C. G. (2006) A cost-effectiveness analysis of tension-free vaginal tape versus laparoscopic mesh colposuspension for primary female stress incontinence. *Acta Obstetrica et Gynecologica Scandinavica*, 85, 1485-1490.
- 134 MANCA, A., SCULPHER, M. J., WARD, K., HILTON, P., MANCA, A., SCULPHER, M. J., WARD, K. & HILTON, P. (2003) A cost-utility analysis of tension-free vaginal tape

- versus colposuspension for primary urodynamic stress incontinence. *BJOG: An International Journal of Obstetrics & Gynaecology*, 110, 255-62.
- 135 DMOCHOWSKI, R. R. & APPELL, R. A. (2000) Injectable agents in the treatment of stress urinary incontinence in women: where are we now? *Urology*, 56, 32-40.
  - 136 HERSCHORN, S., STEELE, D. J. & RADOMSKI, S. B. (1996) Followup of intraurethral collagen for female stress urinary incontinence. *Journal of Urology*, 156, 1305-1309.
  - 137 STEELE, A. C., KOHLI, N. & KARRAM, M. M. (2000) Periurethral collagen injection for stress incontinence with and without urethral hypermobility. *Obstetrics & Gynecology*, 95, 327-331.
  - 138 BENT, A. E., FOOTE, J., SIEGEL, S., FAERBER, G., CHAO, R. & GORMLEY, E. A. (2001) Collagen implant for treating stress urinary incontinence in women with urethral hypermobility. *Journal of Urology*, 166, 1354-1357.
  - 139 LEE, P. E., KUNG, R. C. & DRUTZ, H. P. (2001) Periurethral autologous fat injection as treatment for female stress urinary incontinence: a randomized double-blind controlled trial. *Journal of Urology*, 165, 153-158.
  - 140 CORCOS, J., COLLET, J. P., SHAPIRO, S., HERSCHORN, S., RADOMSKI, S. B., SCHICK, E., GAJEWSKI, J. B., BENEDETTI, A., MACRAMALLAH, E. & HYAMS, B. (2005) Multicenter randomized clinical trial comparing surgery and collagen injections for treatment of female stress urinary incontinence. *Urology*, 65, 898-904.
  - 141 MAHER, C. F., O'REILLY, B. A., DWYER, P. L., CAREY, M. P., CORNISH, A. & SCHLUTER, P. (2005) Pubovaginal sling versus transurethral Macroplastique for stress urinary incontinence and intrinsic sphincter deficiency: a prospective randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*, 112, 797-801.
  - 142 ANDERS, K., KHULLAR, V., CARDOZO, L., BIDMEAD, J., ATHANASIOU, S., TOOZ-HOBSON, P. & ROBINSON, D. (2002) Contigen or macroplastique? A five year follow-up. *International Continence Society, 32nd Annual Meeting. Heidelberg, Germany.*
  - 143 APPELL, R., ROGER, D., ROBERT, M., IRA, K. & HUBBARD, W. (2005) Clinical experience with coaptite® urological bulking agent. *International Continence Society, 33rd annual meeting. Florence, Italy.*
  - 144 LIGHTNER, D., CALVOSA, C., ANDERSEN, R., KLIMBERG, I., BRITO, C. G., SNYDER, J., GLEASON, D., KILLION, D., MACDONALD, J., KHAN, A. U., DIOKNO, A., SIRLS, L. T. & SALTZSTEIN, D. (2001) A new injectable bulking agent for treatment of stress urinary incontinence: results of a multicenter, randomized, controlled, double-blind study of Durasphere. *Urology*, 58, 12-15.
  - 145 ANDERSEN, R. C. (2002) Long-term follow-up comparison of Durasphere and Contigen in the treatment of stress urinary incontinence. *Journal of Lower Genital Tract Disease*, 6, 239-243.
  - 146 DMOCHOWSKI, R., APPELL, R., KLIMBERG, I. & MAYER, R. (2002) Initial clinical results from coaptite injection for stress urinary incontinence comparative clinical study. *International Continence Society, 32nd Annual Meeting. Heidelberg, Germany.*
  - 147 DMOCHOWSKI, R., HERSCHORN, S., CORCOS, J., KARRAM, M., POMMERVILLE, P., BERGER, Y., RADOMSKI, S., JACOBY, K., FOOTE, J., CORNELLA, J., BENT, A. E. & CHAIKIN, D. C. (2002) Multicenter randomized controlled study to evaluate uryx urethral bulking agent in treating female stress urinary incontinence. *International Continence Society, 32nd Annual Meeting. Heidelberg, Germany.*
  - 148 BANO, F., BARRINGTON, J. W. & DYER, R. (2005) Comparison between porcine dermal implant (Permacol) and silicone injection (Macroplastique) for urodynamic stress incontinence. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 16, 147-150.
  - 149 SCHULZ, J. A., NAGER, C. W., STANTON, S. L. & BAESSLER, K. (2004) Bulking agents for stress urinary incontinence: short-term results and complications in a randomized comparison of periurethral and transurethral injections. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 15, 261-265.
  - 150 MAYER, R. D., DMOCHOWSKI, R. R., APPELL, R. A., SAND, P. K., KLIMBERG, I. W., JACOBY, K., GRAHAM, C. W., SNYDER, J. A., NITTI, V. W. & WINTERS, J. C. (2007) Multicenter prospective randomized 52-week trial of calcium hydroxylapatite versus bovine dermal collagen for treatment of stress urinary incontinence. *Urology*, 69, 876-880.
  - 151 GHONIEM, G., BERNHARD, P., CORCOS, J., COMITER, C., TOMERA, K., WESTNEY, O., HERSCHORN, S., LUCENTE, V., SMITH, J., WAHLE, G. & MULCAHY, J. (2005) Multicenter randomised controlled trial to evaluate Macroplastique® urethral bulking agent for the Treatment of female stress urinary incontinence. *International Continence Society, 35th annual meeting. Montreal, Canada.*
  - 152 ABDELWAHAB, H. A., GHONIEM, G. M., ABDELWAHAB, H. A. & GHONIEM, G. M. (2007) Obstructive suburethral mass after transurethral injection of dextranomer/hyaluronic acid copolymer. *International Urogynecology Journal*, 18, 1379-80.
  - 153 HARTANTO, V. H., LIGHTNER, D. J., NITTI, V. W., HARTANTO, V. H., LIGHTNER, D. J. & NITTI, V. W. (2003) Endoscopic evacuation of Durasphere. *Urology*, 62, 135-7.
  - 154 SWEAT, S. D. & LIGHTNER, D. J. (1999) Complications of sterile abscess formation and pulmonary embolism following periurethral bulking agents. *Journal of Urology*, 161, 93-6.
  - 155 PETROU, S. P., PAK, R. W., LIGHTNER, D. J., PETROU, S. P., PAK, R. W. & LIGHTNER, D. J. (2006) Simple aspiration technique to address voiding dysfunction associated with transurethral injection of dextranomer/hyaluronic acid copolymer. *Urology*, 68, 186-8.
  - 156 HAGEMEIER, T., BLAU, U., GAURUDER-BURMESTER, A. & TUNN, R. (2006) [Paraurethral abscess developing after mid-urethral Zuidex-injection in women with stress urinary incontinence -- management of complications and retrospective comparison with bladder neck located injection technique]. *Zentralblatt fur Gynakologie*, 128, 68-70.
  - 157 MADJAR, S., SHARMA, A. K., WALTZER, W. C., FRISCHER, Z., SECREST, C. L., MADJAR, S., SHARMA, A. K., WALTZER, W. C., FRISCHER, Z. & SECREST, C. L. (2006) Periurethral mass formations following bulking agent injection for the treatment of urinary incontinence. *Journal of Urology*, 175, 1408-10.
  - 158 FISCHER, A., ARNOLD, B., SCHELER, P., CASPER, F. & HOFFMANN, G. (2001) [Vault fixation by fascial sling (Williams-Richardson technique) or sacrospinous/sacroctubed fixation (Amreich-Richter technique) - Is there a difference in indications?]. *Zentralblatt fur Gynakologie*, 123, 626-33.
  - 159 BARBALIAS, G., LIATSIKOS, E. & BARBALIAS, D. (1997) Use of slings made of indigenous and allogenic material (Goretex) in type III urinary incontinence and comparison between them. *European Urology*, 31, 394-400.
  - 160 LUCAS, M., EMERY, S. & STEPHENSON, T. (2000) A randomised study to assess and compare the clinical effectiveness of two surgical techniques for the treatment of stress urinary incontinence in women. *Cardiff, The Wales Office of Research and Development for Health and Social Care.*
  - 161 SHIN, M., KIM, J., KOH, J. & JUNG, J. (2001) Comparison of the results of sling procedure using autologous dermal graft patch and cadaveric fascia lata as a sling material for stress urinary incontinence. *International Continence Society, 31st annual meeting. Seoul, Korea.*
  - 162 ARUNKALAIVANAN, A. S. & BARRINGTON, J. W. (2003) Randomized trial of porcine dermal sling (Pelvicol implant) vs. tension-free vaginal tape (TVT) in the surgical treatment of stress incontinence: a questionnaire-based study. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 14, 17-23.

- 163 KONDO, A., KIMURA, K., ISOBE, Y., KAMIHIRA, O. & MATSUURA, O. (2003) A randomised control trial of tension-free vaginal tape in comparison with pubovaginal sling in the treatment of stress incontinence. *Neurourology & Urodynamics*, 22, 485-487 (abstract).
- 164 VISESHSINDH, W., KOCHAKARN, W., WAIKAKUL, W., ROONGRUANGSILP, U., SIRIPORNPINYO, N. & VISESHSINDH, V. (2003) A randomized controlled trial of pubovaginal sling versus vaginal wall sling for stress urinary incontinence. *Journal of the Medical Association of Thailand*, 86, 308-315.
- 165 LUCAS, M., EMERY, S., ALAN, W. & KATHY, W. (2004) Failure of porcine xenograft sling in a randomised controlled trial of three sling materials in surgery for stress incontinence. Joint meeting of International Continence Society & International Urogynecological Association. Paris, France.
- 166 WADIE, B. S., EDWAN, A. & NABEEH, A. M. (2005) Autologous fascial sling vs polypropylene tape at short-term followup: a prospective randomized study. *Journal of Urology*, 174, 990-993.
- 167 GUERRERO, K., WATKINS, A., EMERY, S., WAREHAM, K., STEPHENSON, T., LOGAN, V. & LUCAS, M. (2007) A randomised controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 18, 1263-1270.
- 168 KORDA, A., PEAT, B. & HUNTER, P. (1989) Experience with silastic slings for female urinary incontinence. *Australian & New Zealand Journal of Obstetrics & Gynaecology*, 29, 150-154.
- 169 DUCKETT, J. R. & CONSTANTINE, G. (2000) Complications of silicone sling insertion for stress urinary incontinence. *Journal of Urology*, 163, 1835-1837.
- 170 CHOE, J. M., OGAN, K. & BATTINO, B. S. (2000) Antimicrobial mesh versus vaginal wall sling: a comparative outcomes analysis. *Journal of Urology*, 163, 1829-1834.
- 171 KERSEY, J. (1983) The gauze hammock sling operation in the treatment of stress incontinence. *British Journal of Obstetrics & Gynaecology*, 90, 945-949.
- 172 KERSEY, J., MARTIN, M. R. & MISHRA, P. (1988) A further assessment of the gauze hammock sling operation in the treatment of stress incontinence. *British Journal of Obstetrics & Gynaecology*, 95, 382-385.
- 173 GUNER, H., YILDIZ, A., ERDEM, A., ERDEM, M., TIFTIK, Z. & YILDIRUN, M. (1994) Surgical treatment of urinary stress incontinence by a suburethral sling procedure using a Mersilene mesh graft. *Gynecologic & Obstetric Investigation*, 37, 52-55.
- 174 YOUNG, S. B., HOWARD, A. E. & BAKER, S. P. (2001) Mersilene mesh sling: short- and long-term clinical and urodynamic outcomes. *American Journal of Obstetrics & Gynecology*, 185, 32-40.
- 175 BAI, S. W., JEON, J. D., CHUNG, K. A., KIM, J. Y., KIM, S. K. & PARK, K. H. (2002) The effectiveness of modified six-corner suspension in patients with paravaginal defect and stress urinary incontinence. *International Urogynecology Journal*, 13, 303-7.
- 176 KUO, H. C. (2001) Long-term results of surgical treatment for female stress urinary incontinence. *Urologia Internationalis*, 66, 13-7.
- 177 KAPLAN, S. A., SANTAROSA, R. P. & TE, A. E. (1996) Comparison of fascial and vaginal wall slings in the management of intrinsic sphincter deficiency. *Urology*, 47, 885-889.
- 178 RODRIGUES PALMA, P. C. (2004) Which sling for which patient? *International Urogynecology Journal and Pelvic Floor Dysfunction*, 15, 369-372.
- 179 ABDEL-FATTAH, M., BARRINGTON, J. W. & ARUNKALAIVANAN, A. S. (2004) Pelvicol pubovaginal sling versus tension-free vaginal tape for treatment of urodynamic stress incontinence: a prospective randomized three-year follow-up study. *European Urology*, 46, 629-635.
- 180 WRIGHT, E. J., ISELIN, C. E., CARR, L. K. & WEBSTER, G. D. (1998) Pubovaginal sling using cadaveric allograft fascia for the treatment of intrinsic sphincter deficiency. *Journal of Urology*, 160, 759-762.
- 181 BROWN, S. L. & GOVIER, F. E. (2000) Cadaveric versus autologous fascia lata for the pubovaginal sling: surgical outcome and patient satisfaction. *Journal of Urology*, 164, 1633-1637.
- 182 SOERGEL, T. M., SHOTT, S. & HEIT, M. (2001) Poor surgical outcomes after fascia lata allograft slings. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 12, 247-253.
- 183 FLYNN, B. J. & YAP, W. T. (2002) Pubovaginal sling using allograft fascia lata versus autograft fascia for all types of stress urinary incontinence: 2-year minimum followup. *Journal of Urology*, 167, 608-612.
- 184 O'REILLY, K. J. & GOVIER, F. E. (2002) Intermediate term failure of pubovaginal slings using cadaveric fascia lata: a case series. *Journal of Urology*, 167, 1356-1358.
- 185 ALMEIDA, S. H., GREGORIO, E., GRANDO, J. P., RODRIGUES, M. A., FRAGA, F. C. & MOREIRA, H. A. (2004) Pubovaginal sling using cadaveric allograft fascia for the treatment of female urinary incontinence. *Transplantation Proceedings*, 36, 995-996.
- 186 MCBRIDE, A. W., ELLERKMANN, R. M., BENT, A. E. & MELICK, C. F. (2005) Comparison of long-term outcomes of autologous fascia lata slings with Suspend Tutoplast fascia lata allograft slings for stress incontinence. *American Journal of Obstetrics & Gynecology*, 192, 1677-1681.
- 187 SIMSIMAN, A. J., POWELL, C. R., STRATFORD, R. R. & MENEFEY, S. A. (2005) Suburethral sling materials: best outcome with autologous tissue. *American Journal of Obstetrics & Gynecology*, 193, 2112-2116.
- 188 ULMSTEN, U., HENRIKSSON, L., JOHNSON, P. & VARHOS, G. (1996) An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*, 7, 81-5; discussion 85-6.
- 189 ULMSTEN, U., FALCONER, C., JOHNSON, P., JOMAA, M., LANNER, L., NILSSON, C. G. & OLSSON, I. (1998) A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*, 9, 210-3.
- 190 NILSSON, C. G. (1998) The tension-free vaginal tape procedure (TVT) for treatment of femal urinary incontinence: A minial invasive procedure. *Acta Obstet Gynecol Scand*, 168, 34-37.
- 191 ULMSTEN, U., JOHNSON, P. & REZAPOUR, M. (1999) A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. *Br J Obstet Gynaecol*, 106, 345-50.
- 192 NILSSON, C. G. & KUUVVA, N. (2001) The tension-free vaginal tape procedure is successful in the majority of women with indications for surgical treatment of urinary stress incontinence. *BJOG*, 108, 414-9.
- 193 REZAPOUR, M. & ULMSTEN, U. (2001) Tension free vaginal tape (TVT) in women with recurrent stress incontinence - A long term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct*, 12(Suppl 2) 9-11
- 194 KUUVVA, N. & NILSSON, C. G. (2003) Tension-free vaginal tape procedure: an effective minimally invasive operation for the treatment of recurrent stress urinary incontinence? *Gynecologic & Obstetric Investigation*, 56, 93-98.
- 195 NILSSON, C. G. & KUUVVA, N. (2001) The tension-free vaginal tape procedure is successful in the majority of women with indications for surgical treatment of urinary stress incontinence.[see comment]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 108, 414-9.
- 196 CAMPEAU, L., TU, L. M., LEMIEUX, M. C., NAUD, A., KARSENTY, G., SCHICK, E. & CORCOS, J. (2007) A multicenter, prospective, randomized clinical trial comparing tension-free vaginal tape surgery and no treatment for the management of stress urinary incontinence in elderly women. *Neurourol Urodyn*, 26, 990-4.



- 197 FOOTE, A. J., MAUGHAN, V. & CARNE, C. (2006) Laparoscopic colposuspension versus vaginal suburethral slingplasty: a randomised prospective trial. *Aust N Z J Obstet Gynaecol*, 46, 517-20
- 198 TSENG, L. H., WANG, A. C., LIN, Y. H., LI, S. J., KO, Y. J., TSENG, L.-H., WANG, A. C., LIN, Y.-H., LI, S.-J. & KO, Y.-J. (2005) Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women. *International Urogynecology Journal*, 16, 230-5.
- 199 ANDONIAN, S., CHEN, T., ST-DENIS, B. & CORCOS, J. (2005) Randomized clinical trial comparing suprapubic arch sling (SPARC) and tension-free vaginal tape (TVT): one-year results. *Eur Urol*, 47, 537-41.
- 200 LORD, H. E., TAYLOR, J. D., FINN, J. C., TSOKOS, N., JEFFERY, J. T., ATHERTON, M. J., EVANS, S. F., BREMNER, A. P., ELDER, G. O. & HOLMAN, C. D. (2006) A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence. *BJU Int*, 98, 367-76.
- 201 RECHBERGER, T., RZEZNICZUK, K., SKORUPSKI, P., ADAMIAK, A., TOMASZEWSKI, J., BARANOWSKI, W. & JAKOWICKI, J. A. (2003) A randomized comparison between monofilament and multifilament tapes for stress incontinence surgery. *Int Urogynecol J Pelvic Floor Dysfunct*, 14, 432-6.
- 202 LIM, Y. N., MULLER, R., CORSTIAANS, A., DIETZ, H. P., BARRY, C. & RANE, A. (2005) Suburethral slingplasty evaluation study in North Queensland, Australia: the SUSPEND trial.[see comment]. *Australian & New Zealand Journal of Obstetrics & Gynaecology*, 45, 52-9.
- 203 MESCHIA, M., PIFAROTTI, P., BERNASCONI, F., MAGATTI, F., VIGANO, R., BERTOZZI, R. & BARBACINI, P. (2006) Tension-free vaginal tape (TVT) and intravaginal slingplasty (IVS) for stress urinary incontinence: a multicenter randomized trial. *Am J Obstet Gynecol*, 195, 1338-42.
- 204 WANG, A. C., LEE, L.-Y., LIN, C.-T. & CHEN, J.-R. (2004) A histologic and immunohistochemical analysis of defective vaginal healing after continence taping procedures: a prospective case-controlled pilot study. *American Journal of Obstetrics & Gynecology*, 191, 1868-74.
- 205 KUUVA, N. & NILSSON, C. G. (2002) A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstetrica et Gynecologica Scandinavica*, 81, 72-77.
- 206 TAMUSSINO, K. F., HANZAL, E., KOLLE, D., RALPH, G., RISS, P. A. & AUSTRIAN UROGYNECOLOGY WORKING, G. (2001) Tension-free vaginal tape operation: results of the Austrian registry.[see comment]. *Obstetrics & Gynecology*, 98, 732-6.
- 207 ZULLO, M. A., PLOTTI, F., CALCAGNO, M., MARULLO, E., PALAIA, I., BELLATI, F., BASILE, S., MUZZI, L., ANGIOLI, R. & PANICI, P. B. (2007) One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary
- 208 LIAPIS, A., BAKAS, P., GINER, M. & CREATSAS, G. (2006) Tension-free vaginal tape versus tension-free vaginal tape obturator in women with stress urinary incontinence. *Gynecologic & Obstetric Investigation*, 62, 160-4.
- 209 LAURIKAINEN, E., VALPAS, A., KIVELA, A., KALLIOLA, T., RINNE, K., TAKALA, T. & NILSSON, C. G. (2007) Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial. *Obstetrics & Gynecology*, 109, 4-11.
- 210 ARACO, F., GRAVANTE, G., SORGE, R., OVERTON, J., DE VITA, D., SESTI, F. & PICCIONE, E. (2008) TVT-O vs TVT: a randomized trial in patients with different degrees of urinary stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*, 19, 917-26.
- 211 RINNE, K., LAURIKAINEN, E., KIVALAA, A., AUKEE, P., TAKALA, T., VALPAS, A., NILSSON, C. G. (2008) A randomized trial comparing TVT with TVT-O: 12 months results. *Int Urogynecol J Pelvic Floor Dysfunct*.
- 212 ANDONIAN, S., ST-DENIS, B., LEMIEUX, M. C., CORCOS, J., ANDONIAN, S., ST-DENIS, B., LEMIEUX, M.-C. & CORCOS, J. (2007) Prospective clinical trial comparing Obtape and DUPS to TVT: one-year safety and efficacy results.[see comment]. *European Urology*, 52, 245-51
- 213 PORENA, M., COSTANTINI, E., FREA, B., GIANNANTONI, A., RANZONI, S., MEARINI, L., BINI, V. & KOCJANCIC, E. (2007) Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial. *Eur Urol*, 52, 1481-90.
- 214 Cilaka, V. N., Amu, O., Mayne, C. J.: Factors affecting outcome of colposuspension. *J Obstet Gynaecol*, 22: 72, 2002
- 215 Couillard, D. R., Deckard-Janatpour, K. A., Stone, A. R.: The vaginal wall sling: a compressive suspension procedure for recurrent incontinence in elderly patients. *Urology*, 43: 203, 1994
- 216 Gillon, G., Stanton, S. L.: Long-term follow-up of surgery for urinary incontinence in elderly women. *Br J Urol*, 56: 478, 1984
- 217 Gordon, D., Gold, R., Pauzner, D. et al.: Tension-free vaginal tape in the elderly: is it a safe procedure? *Urology*, 65: 479, 2005
- 218 Sevestre, S., Ciofu, C., Deval, B. et al.: Results of the tension-free vaginal tape technique in the elderly. *Eur Urol*, 44: 128, 2003
- 219 Walsh, K., Generao, S. E., White, M. J. et al.: The influence of age on quality of life outcome in women following a tension-free vaginal tape procedure. *J Urol*, 171: 1185, 2004
- 220 LOWENSTEIN, L., KENTON, K., DOOLEY, Y., E, R. M. & BRUBAKER, L. (2008) Women who experience detrusor overactive at lower bladder volumes report greater bother. *Neurourol Urodyn*, 27, 45-7.
- 221 ANGER, J. T., SAIGAL, C. S., MADISON, R., JOYCE, G. & LITWIN, M. S. (2006) Increasing Costs of Urinary Incontinence Among Female Medicare Beneficiaries. *Journal of Urology*, 176, 247-251.
- 222 ANGER, J. T., LITWIN, M. S., WANG, Q., PASHOS, C. L. & RODRIGUEZ, L. V. (2007) Complications of sling surgery among female Medicare beneficiaries. *Obstetrics & Gynecology*, 109, 707-714.
- 223 WAETJEN, L. E., SUBAK, L. L., SHEN, H., LIN, F., WANG, T. H., VITTINGHOFF, E., BROWN, J. S., WAETJEN, L. E., SUBAK, L. L., SHEN, H., LIN, F., WANG, T.-H., VITTINGHOFF, E. & BROWN, J. S. (2003) Stress urinary incontinence surgery in the United States. *Obstetrics & Gynecology*, 101, 671-6
- 224 KRAUS, S. R., MARKLAND, A., CHAI, T. C., STODDARD, A., FITZGERALD, M. P., LENG, W., MALLETT, V., TENNSTEDT, S. L., URINARY INCONTINENCE TREATMENT, N., Race and ethnicity do not contribute to differences in preoperative urinary incontinence severity or symptom bother in women who undergo stress incontinence surgery. *American Journal of Obstetrics & Gynecology*, 197, 92.e1-6.
- 225 CHILAKA, V. N., AMU, O. & MAYNE, C. J. (2002) Factors affecting outcome of colposuspension. *J Obstet Gynaecol*, 22, 72-4.
- 226 DANESHGARI, F., MOORE, C., DANESHGARI, F. & MOORE, C. (2006) Advancing the understanding of pathophysiological rationale for the treatment of stress urinary incontinence in women: the 'trampoline theory'. *BJU International*, 98 Suppl 1, 8-14; discussion 15-6.
- 227 O'SULLIVAN, D. C., CHILTON, C. P. & MUNSON, K. W. (1995) Should Stamey colposuspension be our primary surgery for stress incontinence? *British Journal of Urology*, 75, 457-460.
- 228 LO, T. S., CHANG, T. C., CHAO, A. S., CHOU, H. H., TSENG, L. H., LIANG, C. C., LO, T.-S., CHANG, T.-C., CHAO, A.-S., CHOU, H.-H., TSENG, L.-H. & LIANG, C.-C. (2003) Tension-free vaginal tape procedure on genuine stress incontinent women with coexisting genital prolapse.



- Acta Obstetrica et Gynecologica Scandinavica, 82, 1049-53.
- 229 SEVESTRE, S., CIOFU, C., DEVAL, B., TRAXER, O., AMARENCO, G. & HAAB, F. (2003) Results of the tension-free vaginal tape technique in the elderly. *Eur Urol*, 44, 128-31.
- 230 BRIEGER, G. & KORDA, A. (1992) The effect of obesity on the outcome of successful surgery for genuine stress incontinence. *Aust N Z J Obstet Gynaecol*, 32, 71-2.
- 231 KJOLHEDE, P., WAHLSTROM, J. & WINGREN, G. (2005) Pelvic floor dysfunction after Burch colposuspension—a comprehensive study. Part I. *Acta Obstetrica et Gynecologica Scandinavica*, 84, 894-901.
- 232 ANGER, J. T., RODRIGUEZ, L. V., WANG, Q., CHEN, E., PASHOS, C. L. & LITWIN, M. S. (2007) Racial disparities in the surgical management of stress incontinence among female Medicare beneficiaries. *J Urol*, 177, 1846-50.
- 233 CUMMINGS, J. M., BOULLIER, J. A. & PARRA, R. O. (1998) Surgical correction of stress incontinence in morbidly obese women.[see comment]. *Journal of Urology*, 160, 754-5.
- 234 GREER, W. J., RICHTER, H. E., BARTOLUCCI, A. A. & BURGIO, K. L. (2008) Obesity and pelvic floor disorders: a systematic review. *Obstet Gynecol*, 112, 341-9.
- 235 SKRIAPAS, K., POULAKIS, V., DILLENBURG, W., DE VRIES, R., WITZSCH, U., MELEKOS, M. & BECHT, E. (2006) Tension-free vaginal tape (TVT) in morbidly obese patients with severe urodynamic stress incontinence as last option treatment. *European Urology*, 49, 544-50.
- 236 ROGERS, R. G., LEBKUCHNER, U., KAMMERER-DOAK, D. N., THOMPSON, P. K., WALTERS, M. D. & NYGAARD, I. E. (2006) Obesity and retropubic surgery for stress incontinence: is there really an increased risk of intraoperative complications? *American Journal of Obstetrics & Gynecology*, 195, 1794-8.
- 237 BLACK, N. A. (1996) Sociodemographic and symptomatic characteristics of women undergoing stress incontinence surgery in the UK. *British Journal of Urology*, 78, 847-855.
- 238 OBRINK, A., FEDOR-FREYBERGH, P., HJELMKVIST, M. & BUNNE, G. (1979) Mental factors influencing recurrence of stress incontinence. *Acta Obstet Gynecol Scand*, 58, 91-4.
- 239 LIAPIS, A., BAKAS, P., LAZARIS, D. & CREATSAS, G. (2004) Tension-free vaginal tape in the management of recurrent stress incontinence. *Arch Gynecol Obstet*, 269, 205-7.
- 240 ROSENZWEIG, B. A., BHATIA, N. N. & NELSON, A. L. (1991) Dynamic urethral pressure profilometry pressure transmission ratio: what do the numbers really mean? *Obstet Gynecol*, 77, 586-90.
- 241 AMAYE-OBU, F. A. & DRUTZ, H. P. (1999) Surgical management of recurrent stress urinary incontinence: A 12-year experience. *Am J Obstet Gynecol*, 181, 1296-307; discussion 1307-9.
- 242 PETROU, S. P. & FRANK, I. (2001) Complications and initial continence rates after a repeat pubovaginal sling procedure for recurrent stress urinary incontinence. *J Urol*, 165, 1979-81.
- 243 KANE, L., CHUNG, T., LAWRIE, H. & ISKAROS, J. (1999) The pubofascial anchor sling procedure for recurrent genuine urinary stress incontinence. *BJU Int*, 83, 1010-4.
- 244 BREEN, J. M., GEER, B. E. & MAY, G. E. (1997) The fascia lata suburethral sling for treating recurrent urinary stress incontinence. *Am J Obstet Gynecol*, 177, 1363-5; discussion 1365-6.
- 245 SU, T. H., HUANG, J. P., WANG, Y. L., YANG, J. M., WEI, H. J. & HUANG, C. L. (1999) Is modified in situ vaginal wall sling operation the treatment of choice for recurrent genuine stress incontinence? *J Urol*, 162, 2073-7.
- 246 RARDIN, C. R., KOHLI, N., ROSENBLATT, P. L., MIKLOS, J. R., MOORE, R. & STROHSNITTER, W. C. (2002) Tension-free vaginal tape: outcomes among women with primary versus recurrent stress urinary incontinence. *Obstet Gynecol*, 100, 893-7.
- 247 Riachi, L, Kohli, N & Miklos, J (2002) Repeat tension-free transvaginal tape (TVT) sling for the treatment of recurrent stress urinary incontinence. *Int Urogynecol J*, 13(2), 133-5.
- 248 Villet, R, Ercoli, A, Atallah, D, Hoffmann, P & Salet-Lizee, D (2002) Second tension-free vaginal tape procedure and mesh retensioning: two possibilities of treatment of recurrent-persistent genuine stress urinary incontinence after a primary tension-free vaginal tape procedure. *Int Urogynecol J & Pelvic Floor Dysfunct*, 13(6), 377-9.
- 249 Lo, TS & Lee, SJ (2004) Treatment of recurrent genuine stress incontinence by shortening previously implanted tension-free vaginal tape. *Acta Obstet Gynecol Scand*, 83(10), 1005-6.
- 250 Paick, JS, Ku, JH, Shin, JW, et al. (2004) Shortening of tension-free vaginal tape for the treatment of recurrent incontinence. *J Urol*, 171(4), 1634.
- 251 NAM, S. B., BAE, J. H. & LEE, J. G. (2007) Surgical considerations for recurrent stress urinary incontinence after the midurethral sling procedure: Redo midurethral sling and shortening of the tape. [Korean]. *Korean Journal of Urology*, 48, 527-535.
- 252 MOORE, R. D., GAMBLE, K. & MIKLOS, J. R. (2007) Tension-free vaginal tape sling for recurrent stress incontinence after transobturator tape sling failure. *International Urogynecology Journal & Pelvic Floor Dysfunction*, 18, 309-313.
- 253 STANTON, SL & CARDOZO, LD (1979) Results of the colposuspension operation for incontinence and prolapse. *Brit J Obstet Gynaecol*, 86(9), 693-7.
- 254 MILANI, R, SCALAMBRINO, S, QUADRI, G, ALGERI, M & MARCHESIN, R (1985) Marshall-Marchetti-Krantz procedure and Burch colposuspension in the surgical treatment of female urinary incontinence. *Brit J Obstet Gynaecol*, 92(10), 1050-3.
- 255 LANGER, R, RON-EL, R, NEUMAN, M, et al. (1988) The value of simultaneous hysterectomy during Burch colposuspension for urinary stress incontinence. *Obstet Gynecol*, 72(6), 866-9.
- 256 GREEN, TH, JR. (1975) Urinary stress incontinence: differential diagnosis, pathophysiology, and management. *Am J Obstet Gynecol*, 122(3), 368-400.
- 257 DARAI, E, JEFFRY, L, DEVAL, B, et al. (2002) Results of tension-free vaginal tape in patients with or without vaginal hysterectomy. *Eur J Obstet Gynecol Repro Biol*, 103(2), 163-7.
- 258 MELTOMAA, SS, HAARALA, MA, TAALIKKA, MO, et al. (2001) Outcome of Burch retropubic urethropexy and the effect of concomitant abdominal hysterectomy: a prospective long-term follow-up study. *Int Urogynecol J & Pelvic Floor Dysfunct*, 12(1), 3-8.
- 259 BAI, SW, KIM, BJ, KIM, SK & PARK, KH (2004) Comparison of outcomes between Burch colposuspension with and without concomitant abdominal hysterectomy. *Yonsei Medical Journal*, 45(4), 665-70.
- 260 ARGIROVIC, R, LIKIC, I, KADIJA, S, et al. (2006) [Outcome of Burch retropubic urethropexy and the effect of concomitant abdominal hysterectomy]. *Acta Chirurgica Iugoslavica*, 53(1), 77-81.
- 261 LOSE, G, JORGENSEN, L & JOHNSEN, A (1988) Predictive value of detrusor instability index in surgery for female urinary incontinence. *Neurourol Urodyn*, 7(2), 141-7.
- 262 POW-SANG, JM, LOCKHART, JL, SUAREZ, A, LANSMAN, H & POLITANO, VA (1986) Female urinary incontinence: preoperative selection, surgical complications and results. *J Urol*, 136(4), 831-3
- 263 SERELS, SR, RACKLEY, RR & APPELL, RA (2000) Surgical treatment for stress urinary incontinence associated with valsalva induced detrusor instability. *J Urol*, 163(3), 884-7.
- 264 KOONINGS, P, BERGMAN, A & BALLARD, CA (1988) Combined detrusor instability and stress urinary incontinence: where is the primary pathology? *Gynecol Obstet Invest*, 26(3), 250-6.

- 265 BOTROS, SM, ABRAMOV, Y, GOLDBERG, RP, et al. (2005) Detrusor overactivity and urge urinary incontinence following midurethral versus bladder sling procedures. *Am J Obstet Gynecol*, 193(6), 2144-8.
- 266 DUCKETT, JR & TAMILSELVI, A (2006) Effect of tension-free vaginal tape in women with a urodynamic diagnosis of idiopathic detrusor overactivity and stress incontinence. *BJOG: Int J Obstet Gynaecol*, 113(1), 30-3.
- 267 CHOE, JH, CHOO, MS & LEE, KS (2008) The impact of tension-free vaginal tape on overactive bladder symptoms in women with stress urinary incontinence: significance of detrusor overactivity.[see comment]. *J Urol*, 179(1), 214-9.
- 269 FRITEL, X., ZABAK, K., PIGNE, A., DEMARIA, F., BENIFLA, J. L., FRITEL, X., ZABAK, K., PIGNE, A., DEMARIA, F. & BENIFLA, J.-L. (2002) Predictive value of urethral mobility before suburethral tape procedure for urinary stress incontinence in women. *Journal of Urology*, 168, 2472-5
- 270 GUTIERREZ BANOS, J. L., MARTIN GARCIA, B., PORTILLO MARTIN, J. A., DEL VALLE SCHAAN, J. I., HERNANDEZ RODRIGUEZ, R., CORREAS GOMEZ, M. A., ROCA EDREIRA, A., RUIZ IZQUIERDO, F. & AGUILERA TUBET, C. (2004) [Usefulness of abdominal leak point pressure determination in the diagnosis of female urinary incontinence in the TVT era]. *Actas Urologicas Espanolas*, 28, 506-12.
- 271 RODRIGUEZ, L. V., DE ALMEIDA, F., DOREY, F. & RAZ, S. (2004) Does Valsalva leak point pressure predict outcome after the distal urethral polypropylene sling? Role of urodynamics in the sling era.[see comment]. *Journal of Urology*, 172, 210-4.
- 272 GORMLEY, E. A. (1998) Outcome measures and surgery for stress urinary incontinence. *Current Opinion in Urology*, 8, 275-278.
- 273 KUJVA, N. & NILSSON, C. G. (2002) A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstetrica et Gynecologica Scandinavica*, 81, 72-77.
- 274 GROUTZ, A., GORDON, D., WOLMAN, I., JAFFA, A. J., DAVID, M. P. & LESSING, J. B. (2002) Tension-free vaginal tape for stress urinary incontinence: Is there a learning curve? *Neurourology & Urodynamics*, 21, 470-2.
- 275 LEBRET, T., LUGAGNE, P. M., HERVE, J. M., BARRE, P., ORSONI, J. L., YONNEAU, L., SAPORTA, F. & BOTTO, H. (2001) Evaluation of tension-free vaginal tape procedure. Its safety and efficacy in the treatment of female stress urinary incontinence during the learning phase. *European Urology*, 40, 543-7.
- 276 MCLENNAN, M. T. & MELICK, C. F. (2005) Bladder perforation during tension-free vaginal tape procedures: analysis of learning curve and risk factors. *Obstetrics & Gynecology*, 106, 1000-4.
- 277 STANTON, S. L., CARDOZO, L., WILLIAMS, J. E., RITCHIE, D. & ALLAN, V. (1978) Clinical and urodynamic features of failed incontinence surgery in the female. *Obstetrics & Gynecology*, 51, 515-520.
- 278 HUANG, K.-H., KUNG, F.-T., LIANG, H.-M., HUANG, L.-Y. & CHANG, S.-Y. (2003) Concomitant surgery with tension-free vaginal tape. *Acta Obstetrica et Gynecologica Scandinavica*, 82, 948-53.
- 279 PARTOLL, L. M. & PARTOLL, L. M. (2002) Efficacy of tension-free vaginal tape with other pelvic reconstructive surgery. *American Journal of Obstetrics & Gynecology*, 186, 1292-5; discussion 1295-8.
- 280 DIGESU, G. A., SALVATORE, S., CHALIHA, C., ATHANASIOU, S., MILANI, R. & KHULLAR, V. (2007) Do overactive bladder symptoms improve after repair of anterior vaginal wall prolapse? *International Urogynecology Journal*, 18, 1439-43.
- 281 FOSTER SR, R. T., BARBER, M. D., PARASIO, M. F. R., WALTERS, M. D., WEIDNER, A. C. & AMUNDSEN, C. L. (2007) A prospective assessment of overactive bladder symptoms in a cohort of elderly women who underwent transvaginal surgery for advanced pelvic organ prolapse. *American Journal of Obstetrics and Gynecology*, 197, 82.e1-82.e4.
- 282 BOYLES, S. H., EDWARDS, R., GREGORY, W., CLARK, A., BOYLES, S. H., EDWARDS, R., GREGORY, W. & CLARK, A. (2007) Complications associated with transobturator sling procedures. *International Urogynecology Journal*, 18, 19-22.
- 283 WEBER, A. M., ABRAMS, P., BRUBAKER, L., CUNDIFF, G., DAVIS, G., DMOCHOWSKI, R. R., FISCHER, J., HULL, T., NYGAARD, I. & WEIDNER, A. C. (2001) The standardization of terminology for researchers in female pelvic floor disorders. *Int Urogynecol J Pelvic Floor Dysfunct*, 12, 178-86.
- 284 DINDO, D., DEMARTINES, N. & CLAVIEN, P.-A. (2004) Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey.[see comment]. *Annals of Surgery*, 240, 205-13.
- 285 DENG, D., RUTMAN, M., RAZ, S. & RODRIGUEZ, L. (2007) Presentation and management of major complications of midurethral slings: Are complications under-reported? *Neurourology and Urodynamics*, 26, 46-52.
- 286 DEVAL, B., LEVARDON, M., SAMAIN, E., RAFII, A., CORTESE, A., AMARENCO, G., CIOFU, C. & HAAB, F. (2003) A French multicenter clinical trial of SPARC for stress urinary incontinence. *European Urology*, 44, 254-258.
- 287 GALLOWAY, N., DAVIES, N. & STEPHENSON, T. P. (1987) The complications of colposuspension. *BJU*, 60, 122-124
- 288 BOUSTEAD, G. B. (2002) The tension-free vaginal tape for treating female stress urinary incontinence. [Review] [43 refs]. *BJU International*, 89, 687-693.
- 289 TAUB, D. A., HOLLENBECK, B. K., WEI, J. T., DUNN, R. L., MCGUIRE, E. J. & LATINI, J. M. (2005) Complications following surgical intervention for stress urinary incontinence: a national perspective. *Neurourology & Urodynamics*, 24, 659-665.
- 290 ADAMS, A., BARDSLEY, A., CRUMLIN, L. & AL., E. (2006) Urinary Incontinence: The management of urinary incontinence in women. IN NATIONAL COLLABORATING CENTRE FOR WOMEN'S AND CHILDRENS HEALTH, N. I. F. H. A. C. E. (Ed.). London, UK, RCOG Press.
- 291 SCHRAFFORDT KOOPS, S. E., BISSELING, T. M., HEINTZ, A. P. & VERVEST, H. A. M. (2005) Prospective analysis of complications of tension-free vaginal tape from The Netherlands Tension-free Vaginal Tape study. *American Journal of Obstetrics & Gynecology*, 193, 45-52.
- 292 ZHU, L., LANG, J., HAI, N. & WONG, F. (2007) Comparing vaginal tape and transobturator tape for the treatment of mild and moderate stress incontinence. *International Journal of Gynaecology & Obstetrics*, 99, 14-7.
- 293 LEE, K. S., HAN, D. H., CHOI, Y. S., YUM, S. H., SONG, S. H., DOO, C. K. & CHOO, M. S. (2007) A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape inside-out for the surgical treatment of female stress urinary incontinence: 1-year followup. *Journal of Urology*, 177, 214-218.
- 294 DAVID-MONTEFIORE, E., FROBERT, J. L., GRISARD-ANAF, M., LIENHART, J., BONNET, K., PONCELET, C., DARAI, E., DAVID-MONTEFIORE, E., FROBERT, J. L., GRISARD-ANAF, M., LIENHART, J., BONNET, K., PONCELET, C. & DARAI, E. (2006) Peri-operative complications and pain after the suburethral sling procedure for urinary stress incontinence: a French prospective randomised multicentre study comparing the retropubic and transobturator routes.[see comment]. *European Urology*, 49, 133-138
- 295 DEBODINANCE, P. (2006) [Trans-obturator urethral sling for surgical correction of female stress urinary incontinence: Outside-in (Monarc) versus inside-out (TVT-O). Are both ways safe?]. [French]. *Journal de Gynecologie, Obstetrique et Biologie de la Reproduction*, 35, 571-577.
- 296 LEE, K. S., CHOO, M. S., LEE, Y. S., HAN, J. Y., KIM, J. Y., JUNG, B. J. & HAN, D. H. (2007) Prospective comparison

- of the 'inside-out' and 'outside-in' transobturator-tape procedures for the treatment of female stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*.
- 297 CETINEL, B., DEMIRKESEN, O., ONAL, B., AKKUS, E., ALAN, C. & CAN, G. (2004) Are there any factors predicting the cure and complication rates of tension-free vaginal tape? *International Urogynecology Journal*, 15, 188-193.
- 298 JEFFRY, L., DEVAL, B., BIRSAN, A., SORIANO, D. & DARAI, E. (2001) Objective and subjective cure rates after tension-free vaginal tape for treatment of urinary incontinence.[see comment]. *Urology*, 58, 702-706
- 299 SULTANA, C. J., CAMPBELL, J. W., PISANELLI, W. S., SIVINSKI, L. & RIMM, A. A. (1997) Morbidity and mortality of incontinence surgery in elderly women: an analysis of Medicare data.[see comment]. *American Journal of Obstetrics & Gynecology*, 176, 344-348.
- 300 ANGER, J. T., LITWIN, M. S., WANG, Q., PASHOS, C. L. & RODRIGUEZ, L. V. (2007) The effect of age on outcomes of sling surgery for urinary incontinence. *Journal of the American Geriatrics Society*, 55, 1927-31.
- 301 ROGERS, R. G., LEBKUCHNER, U., KAMMERER-DOAK, D. N., THOMPSON, P. K., WALTERS, M. D. & NYGAARD, I. E. (2006) Obesity and retropubic surgery for stress incontinence: is there really an increased risk of intraoperative complications? *American Journal of Obstetrics & Gynecology*, 195, 1794-1798.
- 302 MURKHERJEE, K. & CONSTANTINE, G. (2001) Urinary stress incontinence in obese women: tension-free vaginal tape is the answer. *BJU International*, 88, 3.
- 303 LASALA, C. A., SCHIMPF, M. O., UDOH, E., O'SULLIVAN, D. M. & TULIKANGAS, P. (2006) Outcome of tension-free vaginal tape procedure when complicated by intraoperative cystotomy. *American Journal of Obstetrics & Gynecology*, 195, 1857-61.
- 304 HODROFF, M. A., SUTHERLAND, S. E., KESHA, J. B. & SIEGEL, S. W. (2005) Treatment of stress incontinence with the SPARC sling: intraoperative and early complications of 445 patients. *Urology*, 66, 760-762.
- 305 DAVILA, G. W., JOHNSON, J. D. & SERELS, S. (2006) Multicenter experience with the Monarc transobturator sling system to treat stress urinary incontinence. *International Urogynecology Journal*, 17, 460-465.
- 306 BARBER, M. D., GUSTILO-ASHBY, A. M., CHEN, C. C. G., KAPLAN, P., PARAISO, M. F. & WALTERS, M. D. (2006) Perioperative complications and adverse events of the MONARC transobturator tape, compared with the tension-free vaginal tape. *American Journal of Obstetrics & Gynecology*, 195, 1820-1825.
- 307 DETAYRAC, R., DEFFIEUX, X., DRAUPY, S. & AL., E. (2004) A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for the surgical treatment of stress urinary incontinence. *American Journal of Obstetrics & Gynecology*, 190, 6.
- 308 (2007) MAUDE database
- 309 MINAGLIA, S., OZEL, B., KLUTKE, C., BALLARD, C. & KLUTKE, J. (2004) Bladder injury during transobturator sling. *Urology*, 64, 376-377.
- 310 GANDHI, S., ABRAMOV, Y., KWON, C., BEAUMONT, J. L., BOTROS, S., SAND, P. K. & GOLDBERG, R. P. (2006) TVT versus SPARC: comparison of outcomes for two midurethral tape procedures. *International Urogynecology Journal*, 17, 125-130.
- 311 RAJAN, S. & KOHLI, N. (2005) Retropubic hematoma after transobturator sling procedure. *Obstetrics & Gynecology*, 106, 1199-202.
- 312 WALTERS, M. D., TULIKANGAS, P. K., LASALA, C. & MUIR, T. W. (2001) Vascular injury during tension-free vaginal tape procedure for stress urinary incontinence. *Obstetrics & Gynecology*, 98, 957-959.
- 313 KOLLE, D., TAMUSSINO, K., HANZAL, E. & ETAL. (2005) Bleeding complications with the tension-free vaginal tape operation. *American Journal of Obstetrics & Gynecology*, 193, 2045-2049.
- 314 KOBASHI, K. C. & GOVIER, F. E. (2003) Perioperative complications: the first 140 polypropylene pubovaginal slings. *Journal of Urology*, 170, 1918-1921.
- 315 ROUMEGUERE, T., QUACKELS, T. & BOSSCHE, M. V. (2005) Trans-obturator vaginal tape (TOT) for female stress incontinence: one year follow-up in 120 patients. *European Urology*, 48, 805-809.
- 316 TSIVIAN, A., MOGUTIN, B., KESSLER, O., KORCZAK, D., LEVIN, S. & SIDI, A. A. (2004) Tension-free vaginal tape procedure for the treatment of female stress urinary incontinence: long-term results. *Journal of Urology*, 172, 998-1000.
- 317 MESCHIA, M., PIFAROTTI, P., BERNASCONI, F., GUERCIO, E., MAFFIOLINI, M., MAGATTI, F. & SPREAFICO, L. (2001) Tension-Free vaginal tape: analysis of outcomes and complications in 404 stress incontinent women. *International Urogynecology Journal*, 12 Suppl 2, S24-S27.
- 318 LEVIN, I., GROUTZ, A., GOLD, R., PAUZNER, D., LESSING, J. B. & GORDON, D. (2004) Surgical complications and medium-term outcome results of tension-free vaginal tape: a prospective study of 313 consecutive patients. *Neurourology & Urodynamics*, 23, 7-9.
- 319 ABOUASSALY, R., STEINBERG, J. R., LEMIEUX, M., MAROIS, C., GILCHRIST, L. I., BOURQUE, J. L., TU, L. M. & CORCOS, J. (2004) Complications of tension-free vaginal tape surgery: a multi-institutional review. *BJU International*, 94, 110-113.
- 320 MOSS, E., TOOZS-HOBSON, P., CARDOZO, L., EMENS, M., POGMORE, J. R., CONSTANTINE, G. (2002) A multicentre review of the tension-free vaginal tape procedure in clinical practice. *Journal of Obstetrics & Gynaecology*, 22, 519-522.
- 321 DIETZ, H. P., BARRY, C., LIM, Y. & RANE, A. (2006) TVT vs Monarc: a comparative study. *International Urogynecology Journal*, 17, 566-569.
- 322 MOREY, A. F., MEDENDORP, A. R., NOLLER, M. W., MORA, R. V., SHANDERA, K. C., FOLEY, J. P., RIVERA, L. R., REYNA, J. A. & TERRY, P. J. (2006) Transobturator versus transabdominal mid urethral slings: a multi-institutional comparison of obstructive voiding complications. *Journal of Urology*, 175, 1014-1017.
- 323 MISHRA, V. C., MISHRA, N., KARIM, O. M. A. & MOTIWALA, H. G. (2005) Voiding dysfunction after tension-free vaginal tape: a conservative approach is often successful. *International Urogynecology Journal*, 16, 210-214.
- 324 LENG, W. W., DAVIES, B. J., TARIN, T., SWEENEY, D. D. & CHANCELLOR, M. B. (2004) Delayed treatment of bladder outlet obstruction after sling surgery: association with irreversible bladder dysfunction. *Journal of Urology*, 172, 1379-1381.
- 325 STARKMAN, J. S., DUFFY III, J., WOLTER, C. E., KAUFMAN, M. R., SCARPERO, H. M. & DMOCHOWSKI, R. R. (2007) The evolution of obstruction-induced overactive bladder (OAB) symptoms following urethrolisis for female bladder outlet obstruction.
- 326 GOLDMAN, H. B. & GOLDMAN, H. B. (2003) Simple sling incision for the treatment of iatrogenic urethral obstruction. [Review] [13 refs]. *Urology*, 62, 714-718.
- 327 KLUTKE, C., SIEGEL, S., CARLIN, B., PASZKIEWICZ, E., KIRKEMO, A. & KLUTKE, J. (2001) Urinary retention after tension-free vaginal tape procedure: incidence and treatment. *Urology*, 58, 697-701.
- 328 NITTI, V. W., CARLSON, K. V., BLAIVAS, J. G. & DMOCHOWSKI, R. R. (2002) Early results of pubovaginal sling lysis by midline sling incision. *Urology*, 59, 47-51.
- 329 CARR, L. K. & WEBSTER, G. D. (1997) Voiding dysfunction following incontinence surgery: diagnosis and treatment with retropubic or vaginal urethrolisis.[see comment]. *Journal of Urology*, 157, 821-823.
- 330 ROMANZI, L. J. & BLAIVAS, J. G. (2000) Protracted urinary retention necessitating urethrolisis following tension-free



- vaginal tape surgery.[see comment]. *Journal of Urology*, 164, 2022-2023.
- 331 PETROU, S. P., BROWN, J. A. & BLAIVAS, J. G. (1999) Suprameatal transvaginal urethrolysis. *Journal of Urology*, 161, 1268-1271.
- 332 GOLDMAN, H. B., RACKLEY, R. R. & APPELL, R. A. (1999) The efficacy of urethrolysis without re-suspension for iatrogenic urethral obstruction. *Journal of Urology*, 161, 196-198.
- 333 STARKMAN, J. S. W., C., GOMELSKY, A., SCARPERO, H., AND DMOCHOWSKI (2006) Voiding dysfunction following removal of eroded synthetic midurethral slings. *Journal of Urology*, 176, 4.
- 334 ABDEL-FATTAH, M., SIVANESAN, K., RAMSAY, I., PRINGLE, S. & BJORNSSON, S. (2006) How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure. *BJU International*, 98, 594-598.
- 335 KOBASHI, K. C., DMOCHOWSKI, R., MEE, S. L., MOSTWIN, J., NITTI, V. W., ZIMMERN, P. E. & LEACH, G. E. (1999) Erosion of woven polyester pubovaginal sling.[see comment]. *Journal of Urology*, 162, 2070-2.
- 336 FEIFER, A. & CORCOS, J. (2007) The use of synthetic sub-urethral slings in the treatment of female stress urinary incontinence. *International Urogynecology Journal*, 18, 1087-95.
- 337 GLAVIND, K. & SANDER, P. (2004) Erosion, defective healing and extrusion after tension-free urethropexy for the treatment of stress urinary incontinence. *International Urogynecology Journal*, 15, 179-182.
- 338 DE BOER, F. & DE BOER, F. (2005) Multifilament polypropylene mesh for urinary incontinence: 10 cases of infections requiring removal of the sling.[comment]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 112, 1456.
- 339 SIEGEL, A. L., KIM, M., GOLDSTEIN, M., LEVEY, S. & ILBEIGI, P. (2005) High incidence of vaginal mesh extrusion using the intravaginal slingplasty sling.[see comment]. *Journal of Urology*, 174, 1308-1311.
- 340 SIEGEL, A. L. & SIEGEL, A. L. (2005) Vaginal mesh extrusion associated with use of Mentor transobturator sling. *Urology*, 66, 995-999.
- 341 YAMADA, B. S., GOVIER, F. E., STEFANOVIC, K. B. & KOBASHI, K. C. (2006) High rate of vaginal erosions associated with the mentor ObTape.[see comment]. *Journal of Urology*, 176, 651-654
- 342 ROBERT, M., MURPHY, M., BIRCH, C., SWABY, C. & ROSS, S. (2006) Five cases of tape erosion after transobturator surgery for urinary incontinence. *Obstetrics & Gynecology*, 107, 472-474.
- 343 KOBASHI, K. C. & GOVIER, F. E. (2003) Management of vaginal erosion of polypropylene mesh slings. *Journal of Urology*, 169, 2242-2243.
- 344 GOLOMB, J., GROUTZ, A., MOR, Y., LEIBOVITCH, I. & RAMON, J. (2001) Management of urethral erosion caused by a pubovaginal fascial sling. *Urology*, 57, 159-160.
- 345 AMUNDSEN, C. L., FLYNN, B. J. & WEBSTER, G. D. (2003) Urethral erosion after synthetic and nonsynthetic pubovaginal slings: differences in management and continence outcome. *Journal of Urology*, 170, 134-137.
- 346 HAMMAD, F. T., KENNEDY-SMITH, A. & ROBINSON, R. G. (2005) Erosions and urinary retention following polypropylene synthetic sling: Australasian survey. *European Urology*, 47, 641-646.
- 347 GIRI, S. K., DRUMM, J. & FLOOD, H. D. (2005) Endoscopic holmium laser excision of intravesical tension-free vaginal tape and polypropylene suture after anti-incontinence procedures.[see comment]. *Journal of Urology*, 174, 1306-1307.
- 348 HODROFF, M., PORTIS, A. & SIEGEL, S. W. (2004) Endoscopic removal of intravesical polypropylene sling with the holmium laser. *Journal of Urology*, 172, 1361-1362.
- 349 SHAFFER, B. S. (1995) Pearls and perils of patient positioning. *AUA Update Series*, 14, 178-183.
- 350 VERVEST, H. A. M., BONGERS, M. Y. & VAN DER WURFF, A. A. M. (2006) Nerve injury: an exceptional cause of pain after TVT. *International Urogynecology Journal*, 17, 665-667.
- 351 RACKLEY, R. R., ABDELMALAK, J. B., MADJAR, S., YANILMAZ, A., APPELL, R. A. & TCHETGEN, M. B. (2001) Bone anchor infections in female pelvic reconstructive procedures: a literature review of series and case reports. *Journal of Urology*, 165, 1975-1978.
- 352 ENZLER, M., AGINS, H. J., KOGAN, M., KUDURNA, J., SAND, P., WURTZ, R. & CULLIGAN, P. (1999) Osteomyelitis of the pubis following suspension of the neck of the bladder with use of bone anchors. A report of four cases. *Journal of Bone & Joint Surgery - American Volume*, 81, 1736-1740.
- 353 FITZGERALD, M. P., GITELIS, S. & BRUBAKER, L. (1999) Pubic osteomyelitis and granuloma after bone anchor placement. *International Urogynecology Journal*, 10, 346-348.
- 354 FRANKS, M. E., LAVELLE, J. P., YOKOYAMA, T., CHUANG, Y. C. & CHANCELLOR, M. B. (2000) Metastatic osteomyelitis after pubovaginal sling using bone anchors. *Urology*, 56, 330-331.
- 355 GRAHAM, C. W. & DMOCHOWSKI, R. R. (2002) Pubic osteomyelitis following bladder neck surgery using bone anchors: A report of 9 cases. *Journal of Urology*, 168, 2055-2058
- 356 JONES, L. R. A. (2002) The use of validated questionnaires to assess female sexual dysfunction. [Review] [18 refs]. *World Journal of Urology*, 20, 89-92.
- 356 LEMACK, G. E. & ZIMMERN, P. E. (2000) Sexual function after vaginal surgery for stress incontinence: results of a mailed questionnaire. *Urology*, 56, 223-227.
- 357 MAZOUNI, C., KARSENTY, G., BRETTELLE, F., BLADOU, F., GAMERRE, M. & SERMENT, G. (2004) Urinary complications and sexual function after the tension-free vaginal tape procedure. *Acta Obstetrica et Gynecologica Scandinavica*, 83, 955-961.
- 358 SHAH, S. M., BUKKAPATNAM, R. & RODRIGUEZ, L. V. (2005) Impact of vaginal surgery for stress urinary incontinence on female sexual function: is the use of polypropylene mesh detrimental? *Urology*, 65, 270-274.
- 359 GLAVIND, K. & TETSCHKE, M. S. (2004) Sexual function in women before and after suburethral sling operation for stress urinary incontinence: a retrospective questionnaire study. *Acta Obstetrica et Gynecologica Scandinavica*, 83, 965-968.
- 360 BABALOLA, E. O., FAMUYIDE, A. O., MCGUIRE, L. J., GEBHART, J. B. & KLINGELE, C. J. (2006) Vaginal erosion, sinus formation, and ischiorectal abscess following transobturator tape: ObTape implantation. *International Urogynecology Journal*, 17, 418-21.
- 361 BENASSI, G., MARCONI, L., ACCORSI, F., ANGELONI, M. & BENASSI, L. (2007) Abscess formation at the ischiorectal fossa 7 months after the application of a synthetic transobturator sling for stress urinary incontinence in a type II diabetic woman. *International Urogynecology Journal*, 18, 697-9.
- 363 BUSBY, G. & BROOME, J. (2007) Necrotising fasciitis following unrecognised bladder injury during transobturator sling procedure.[erratum appears in *BJOG*. 2007 Mar;114(3):381]. *BJOG: An International Journal of Obstetrics & Gynaecology*, 114, 111-2.
- 364 DEFFIEUX, X., DONNADIEU, A. C., MORDEFROID, M., LEVANTE, S., FRYDMAN, R. & FERNANDEZ, H. (2007) Prepubic and thigh abscess after successive placement of two suburethral slings. *International Urogynecology Journal*, 18, 571-4.
- 365 GOLDMAN, H. B. (2006) Large thigh abscess after placement of synthetic transobturator sling. *International Urogynecology Journal*, 17, 295-6.
- 366 STOTHERS, L., GOLDENBERG, S. L. & LEONE, E. F.



- (1998) Complications of periurethral collagen injection for stress urinary incontinence. *Journal of Urology*, 159, 806-807.
- 367 KARRAM, M. M., SEGAL, J. L., VASSALLO, B. J. & KLEEMAN, S. D. (2003) Complications and untoward effects of the tension-free vaginal tape procedure. *Obstetrics & Gynecology*, 101, 929-932.
- 368 MALIZIA, A. A., JR., REIMAN, H. M., MYERS, R. P., SANDE, J. R., BARHAM, S. S., BENSON, R. C., JR., DEWANJEE, M. K. & UTZ, W. J. (1984) Migration and granulomatous reaction after periurethral injection of polytef (Teflon). *JAMA*, 251, 3277-3281.
- 369 AARONSON, I. A., RAMES, R. & GREENE, W. (1993) Endoscopic treatment of reflux: migration of Teflon to the lungs and brain. *Eur Urol* 23, 5.
- 370 PANNEK, J., BRANDS, F. H. & SENGE, T. (2001) Particle migration after transurethral injection of carbon coated beads for stress urinary incontinence. *Journal of Urology*, 166, 1350-3.
- 371 HURTADO, E. A., MCCRERY, R. G. & APPELL, R. A. (2007) Complications of ethylene vinyl alcohol copolymer s an off-label intra-urethral bulking agent in men with stress urinary incontinence.
- 372 ABRAMS, P., CARDOZO, L., FALL, M., GRIFFITHS, D., ROSIER, P., ULMSTEN, U., VAN KERREBROECK, P., VICTOR, A., WEIN, A. & STANDARDISATION SUB-COMMITTEE OF THE INTERNATIONAL CONTINENCE, S. (2002) The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. *Neurourology & Urodynamics*, 21, 167-178.
- 373 STEWART, W. F., VAN ROOYEN, J. B., CUNDIFF, G. W., ABRAMS, P., HERZOG, A. R., COREY, R., HUNT, T. L. & WEIN, A. J. (2003) Prevalence and burden of overactive bladder in the United States. *World Journal of Urology*, 20, 327-336.
- 374 CHAPPLE, C. R. & BRYAN, N. P. (1998) Surgery for detrusor overactivity. *World J Urol*, 16, 268-73.
- 375 APPELL, R. A. (1998) Surgery for the treatment of overactive bladder. [Review] [28 refs]. *Urology*, 51, 27-29.
- 376 HASAN, S. T., MARSHALL, C., ROBSON, W. A. & NEAL, D. E. (1995) Clinical outcome and quality of life following enterocystoplasty for idiopathic detrusor instability and neurogenic bladder dysfunction.[comment]. *British Journal of Urology*, 76, 551-557.
- 377 HERSCHORN, S. & HEWITT, R. J. (1998) Patient perspective of long-term outcome of augmentation cystoplasty for neurogenic bladder. *Urology*, 52, 672-678.
- 378 PARSONS, K. F., MACHIN, D. G., WOOLFENDEN, K. A., WALMSLEY, B., ABERCROMBIE, G. F. & VINNICOMBE, J. (1984) Endoscopic bladder transection. *British Journal of Urology*, 56, 625-628.
- 379 HASAN, S. T., ROBSON, W. A., RAMSDEN, P. D., ESSENHIGH, D. M. & NEAL, D. E. (1995) Outcome of endoscopic bladder transection. *British Journal of Urology*, 75, 592-596.
- 380 LUCAS, M. G. & THOMAS, D. G. (1987) Endoscopic bladder transection for detrusor instability. *British Journal of Urology*, 59, 526-528.
- 381 HELMSTEIN, K. (1972) Treatment of bladder carcinoma by a hydrostatic pressure technique. Report on 43 cases. *British Journal of Urology*, 44, 434-450.
- 382 RAMSDEN, P. D., SMITH, J. C., DUNN, M. & ARDRAN, G. M. (1976) Distension therapy for the unstable bladder: later results including an assessment of repeat distensions. *British Journal of Urology*, 48, 623-629.
- 383 DUNN, M., SMITH, J. C. & ARDRAN, G. M. (1974) Prolonged bladder distension as a treatment of urgency and urge incontinence of urine. *British Journal of Urology*, 46, 645-652.
- 384 DELAERE, K. P., DEBRUYNE, F. M., MICHIELS, H. G. & MOONEN, W. A. (1980) Prolonged bladder distension in the management of the unstable bladder. *Journal of Urology*, 124, 334-337.
- 385 WHITFIELD, H. N. & MAYO, M. E. (1975) Prolonged bladder distension in the treatment of the unstable bladder. *British Journal of Urology*, 47, 635-639.
- 386 PENGELLY, A. W., STEPHENSON, T. P., MILROY, E. J., WHITESIDE, C. G. & TURNER-WARWICK, R. (1978) Results of prolonged bladder distension as treatment for detrusor instability. *British Journal of Urology*, 50, 243-245.
- 387 PARKHOUSE, H. F., GILPIN, S. A., GOSLING, J. A. & TURNER-WARWICK, R. T. (1987) Quantitative study of phenol as a neurolytic agent in the urinary bladder.[erratum appears in Br J Urol 1988 Aug;62(2):193-4]. *British Journal of Urology*, 60, 410-412.
- 388 EWING, R., BULTITUDE, M. I. & SHUTTLEWORTH, K. E. (1982) Subtrigonal phenol injection for urge incontinence secondary to detrusor instability in females. *British Journal of Urology*, 54, 689-692.
- 389 EWING, R., BULTITUDE, M. I. & SHUTTLEWORTH, K. E. (1983) Subtrigonal phenol injection therapy for incontinence in female patients with multiple sclerosis. *Lancet*, 1, 1304-1306.
- 390 CAMERON-STRANGE, A. & MILLARD, R. J. (1988) Management of refractory detrusor instability by transvesical phenol injection. *British Journal of Urology*, 62, 323-325.
- 391 BLACKFORD, H. N., MURRAY, K., STEPHENSON, T. P. & MUNDY, A. R. (1984) Results of transvesical infiltration of the pelvic plexuses with phenol in 116 patients. *British Journal of Urology*, 56, 647-649.
- 392 CHAPPLE, C. R., HAMPSON, S. J., TURNER-WARWICK, R. T. & WORTH, P. H. (1991) Subtrigonal phenol injection. How safe and effective is it?. [Review] [16 refs]. *British Journal of Urology*, 68, 483-486.
- 393 RAMSAY, I. N., CLANCY, S. & HILTON, P. (1992) Subtrigonal phenol injections in the treatment of idiopathic detrusor instability in the female--a long-term urodynamic follow-up. *British Journal of Urology*, 69, 363-365.
- 394 WALL, L. L. & STANTON, S. L. (1989) Transvesical phenol injection of pelvic nerve plexuses in females with refractory urge incontinence. *British Journal of Urology*, 63, 465-468.
- 395 ROSENBAUM, T. P., SHAW, P. J. & WORTH, P. H. (1990) Trans-trigonal phenol failed the test of time. *British Journal of Urology*, 66, 164-16
- 396 HODGKINSON, C. P. & DRUKKER, B. H. (1977) Infravesical nerve resection for detrusor dyssynergia. The Ingelman-Sundberg operation. *Acta Obstetricia et Gynecologica Scandinavica*, 56, 401-408.
- 397 CESPEDES, R. D., CROSS, C. A. & MCGUIRE, E. J. (1996) Modified Ingelman-Sundberg bladder denervation procedure for intractable urge incontinence.[comment]. *Journal of Urology*, 156, 1744-1747.
- 398 WESTNEY, O. L., LEE, J. T., MCGUIRE, E. J., PALMER, J. L., CESPEDES, R. D. & AMUNDSEN, C. L. (2002) Long-term results of Ingelman-Sundberg denervation procedure for urge incontinence refractory to medical therapy. *Journal of Urology*, 168, 1044-1047.
- 399 JUANG, C.-M., YU, K.-J., CHOU, P., YEN, M.-S., TWU, N.-F., HORNG, H.-C. & HSU, W.-L. (2007) Efficacy analysis of trans-obturator tension-free vaginal tape (TVT-O) plus modified Ingelman-Sundberg procedure versus TVT-O alone in the treatment of mixed urinary incontinence: a randomized study. *European Urology*, 51, 1671-8; discussion 1679.
- 400 GOLDWASSER, B. & WEBSTER, G. D. (1986) Augmentation and substitution enterocystoplasty. [Review] [54 refs]. *Journal of Urology*, 135, 215-224.
- 401 GOUGH, D. C. (2001) Enterocystoplasty. [Review] [40 refs]. *BJU International*, 88, 739-743.
- 402 GREENWELL, T. J., VENN, S. N. & MUNDY, A. R. (2001) Augmentation cystoplasty. [Review] [166 refs]. *BJU International*, 88, 511-525.
- 403 NIKNEJAD, K. G. & ATALA, A. (2000) Bladder augmentation

- techniques in women. [Review] [146 refs]. *International Urogynecology Journal*, 11, 156-169.
- 404 DUEL, B. P., GONZALEZ, R. & BARTHOLD, J. S. (1998) Alternative techniques for augmentation cystoplasty. [Review] [134 refs]. *Journal of Urology*, 159, 998-1005.
- 405 AWAD, S. A., AL ZAHRANI, H. M., GAJEWSKI, J. B. & BOURQUE-KEHOE, A. A. (1998) Long-term results and complications of augmentation ileocystoplasty for idiopathic urge incontinence in women.[comment]. *British Journal of Urology*, 81, 569-573.
- 406 BRAMBLE, F. J. (1982) The treatment of adult enuresis and urge incontinence by enterocystoplasty. *British Journal of Urology*, 54, 693-696.
- 407 GEORGE, V. K., RUSSELL, G. L., SHUTT, A., GACHES, C. G. & ASHKEN, M. H. (1991) Clam ileocystoplasty. *British Journal of Urology*, 68, 487-489.
- 408 KELLY, J. D. & KEANE, P. F. (1998) Long-term results and complications of augmentation ileocystoplasty for idiopathic urge incontinence in women.[comment]. *British Journal of Urology*, 82, 609-610.
- 409 KELLY, J. D., KERNOHAN, R. M. & KEANE, P. F. (1997) Symptomatic outcome following clam ileocystoplasty. *European Urology*, 32, 30-33.
- 410 KOCKELBERGH, R. C., TAN, J. B., BATES, C. P., BISHOP, M. C., DUNN, M. & LEMBERGER, R. J. (1991) Clam enterocystoplasty in general urological practice. *British Journal of Urology*, 68, 38-41.
- 411 MUNDY, A. R. & STEPHENSON, T. P. (1985) "Clam" ileocystoplasty for the treatment of refractory urge incontinence. *British Journal of Urology*, 57, 641-646.
- 412 LENG, W. W., BLALOCK, H. J., FREDRIKSSON, W. H., ENGLISH, S. F. & MCGUIRE, E. J. (1999) Enterocystoplasty or detrusor myectomy? Comparison of indications and outcomes for bladder augmentation. *Journal of Urology*, 161, 758-763.
- 413 CARTWRIGHT, P. C. & SNOW, B. W. (1989) Bladder autoaugmentation: early clinical experience. *Journal of Urology*, 142, 505-508.
- 414 CARTWRIGHT, P. C. & SNOW, B. W. (1989) Bladder autoaugmentation: partial detrusor excision to augment the bladder without use of bowel. *Journal of Urology*, 142, 1050-1053.
- 415 DEWAN, P. A. (1998) Autoaugmentation demucosalized enterocystoplasty. *World Journal of Urology*, 16, 255-261.
- 416 TER MEULEN, P. H., HEESAKKERS, J. P. & JANKNEG, R. A. (1997) A study on the feasibility of vesicomatomy in patients with motor urge incontinence. *European Urology*, 32, 166-169.
- 417 MACNEILY, A. E., AFSHAR, K., COLEMAN, G. U. & JOHNSON, H. W. (2003) Autoaugmentation by detrusor myotomy: its lack of effectiveness in the management of congenital neuropathic bladder. *Journal of Urology*, 170, 1643-1646.
- 418 MARTE, A., DI MEGLIO, D., COTRUFO, A. M., DI IORIO, G., DE PASQUALE, M. & VESSELLA, A. (2002) A long-term follow-up of autoaugmentation in myelodysplastic children. *BJU International*, 89, 928-931.
- 419 CLOSE, C. E. (2001) Autoaugmentation gastrocystoplasty. [Review] [23 refs]. *BJU International*, 88, 757-761.
- 420 DEWAN, P. A. & STEFANEK, W. (1994) Autoaugmentation gastrocystoplasty: early clinical results. *British Journal of Urology*, 74, 460-464.
- 421 OGE, O., TEKGUL, S., ERGEN, A. & KENDI, S. (2000) Urothelium-preserving augmentation cystoplasty covered with a peritoneal flap. *BJU International*, 85, 802-805.
- 422 PEROVIC, S. V., DJORDJEVIC, M. L., KEKIC, Z. K. & VUKADINOVIC, V. M. (2002) Bladder autoaugmentation with rectus muscle backing. *Journal of Urology*, 168, 1877-1880.
- 423 SHEKARRIZ, B., UPADHYAY, J., DEMIRBILEK, S., BARTHOLD, J. S. & GONZALEZ, R. (2000) Surgical complications of bladder augmentation: comparison between various enterocystoplasties in 133 patients. *Urology*, 55, 123-128.
- 424 ATALA, A. (2000) Tissue engineering for bladder substitution. [Review] [52 refs]. *World Journal of Urology*, 18, 364-370
- 425 ATALA, A. (2001) Bladder regeneration by tissue engineering. *BJU International*, 88, 765-770.
- 426 ATALA, A., BAUER, S. B., SOKER, S., YOO, J. J. & RETIK, A. B. (2006) Tissue-engineered autologous bladders for patients needing cystoplasty. *Lancet*, 367, 1241-6.
- 427 GILLON, G. & MUNDY, A. R. (1989) The dissolution of urinary mucus after cystoplasty. *British Journal of Urology*, 63, 372-374.
- 428 BARRINGTON, J. W., FULFORD, S., GRIFFITHS, D. & STEPHENSON, T. P. (1997) Tumors in bladder remnant after augmentation enterocystoplasty. *Journal of Urology*, 157, 482-485.
- 429 FILMER, R. B. & SPENCER, J. R. (1990) Malignancies in bladder augmentations and intestinal conduits. [Review] [98 refs]. *Journal of Urology*, 143, 671-678.
- 430 GOLOMB, J., KLUTKE, C. G. & RAZ, S. (1989) Complications of bladder substitution and continent urinary diversion. [Review] [53 refs]. *Urology*, 34, 329-338.
- 431 TANAGHO, E. A. (1981) Bladder neck reconstruction for total urinary incontinence: 10 years experience. *J Urol*, 125, 321-6.
- 432 SCHMIDT, R. A., JONAS, U., OLESON, K. A., JANKNEG, R. A., HASSOUNA, M. M., SIEGEL, S. W. & VAN KERREBROECK, P. E. (1999) Sacral nerve stimulation for treatment of refractory urinary urge incontinence. *Sacral Nerve Stimulation Study Group. Journal of Urology*, 162, 352-357.
- 433 HASSOUNA, M. M., SIEGEL, S. W., NYEHOLT, A. A., ELHILALI, M. M., VAN KERREBROECK, P. E., DAS, A. K., GAJEWSKI, J. B., JANKNEG, R. A., RIVAS, D. A., DIJKEMA, H., MILAM, D. F., OLESON, K. A. & SCHMIDT, R. A. (2000) Sacral neuromodulation in the treatment of urgency-frequency symptoms: a multicenter study on efficacy and safety. *Journal of Urology*, 163, 1849-1854.
- 434 JONAS, U., FOWLER, C. J., CHANCELLOR, M. B., ELHILALI, M. M., FALL, M., GAJEWSKI, J. B., GRUNEWALD, V., HASSOUNA, M. M., HOMBERG, U., JANKNEG, R., VAN KERREBROECK, P. E., LYCKLAMA ANIJEHOLT, A. A., SIEGEL, S. W. & SCHMIDT, R. A. (2001) Efficacy of sacral nerve stimulation for urinary retention: results 18 months after implantation. *J Urol*, 165, 15-9.
- 435 SIEGEL, S. W., CATANZARO, F., DIJKEMA, H. E., ELHILALI, M. M., FOWLER, C. J., GAJEWSKI, J. B., HASSOUNA, M. M., JANKNEG, R. A., JONAS, U., VAN KERREBROECK, P. E., LYCKLAMA ANIJEHOLT, A. A., OLESON, K. A. & SCHMIDT, R. A. (2000) Long-term results of a multicenter study on sacral nerve stimulation for treatment of urinary urge incontinence, urgency-frequency, and retention. *Urology*, 56, 87-91.
- 436 PETTIT, P. D., THOMPSON, J. R. & CHEN, A. H. (2002) Sacral neuromodulation: new applications in the treatment of female pelvic floor dysfunction. *Curr Opin Obstet Gynecol*, 14, 521-5.
- 437 SPINELLI, M., BERTAPPELLE, P., CAPPELLANO, F., ZANOLLO, A., CARONE, R., CATANZARO, F., GIARDIELLO, G., DE SETA, F. & GINS, G. (2001) Chronic sacral neuromodulation in patients with lower urinary tract symptoms: results from a national register. *Journal of Urology*, 166, 541-545.
- 438 HEDLUND, H., SCHULTZ, A., TALSETH, T., TONSETH, K. & VAN DER HAGEN, A. (2002) Sacral neuromodulation in Norway: clinical experience of the first three years. *Scandinavian Journal of Urology & Nephrology Supplementum*, 87-95.
- 439 GILLON, G. & MUNDY, A. R. (1989) The dissolution of urinary mucus after cystoplasty. *British Journal of Urology*, 63, 372-374.
- 440 GOVIER, F. E. & KOBASHI, K. (2001) Pubovaginal slings: a review of the technical variables. *Current Opinion in Urology*, 11, 405-10.

- 441 HIJAZ, A., VASAVADA, S. P., DANESHGARI, F., FRINJARI, H., GOLDMAN, H. & RACKLEY, R. (2006) Complications and troubleshooting of two-stage sacral neuromodulation therapy: a single-institution experience. *Urology*, 68, 533-537.
- 442 SCHMIDT, R. A., JONAS, U., OLESON, K. A., JANKNEG, R. A., HASSOUNA, M. M., SIEGEL, S. W. & VAN KERREBROECK, P. E. (1999) Sacral nerve stimulation for treatment of refractory urinary urge incontinence. Sacral Nerve Stimulation Study Group. *Journal of Urology*, 162, 352-357.
- 443 SEIGEL, S. W., CATANZANO, F., DIJKEMA, H. & ET AL. (2000) Long-term results of a multicenter study on sacral nerve stimulation for treatment of urinary urge incontinence, urgency-frequency and retention. *Urology*, 56 (Suppl.6), 87-91.
- 444 WEIL, E. H., RUIZ-CERDA, J. L., EERDMANS, P. H., JANKNEG, R. A., BEMELMANS, B. L. & VAN KERREBROECK, P. E. (2000) Sacral root neuromodulation in the treatment of refractory urinary urge incontinence: a prospective randomized clinical trial. *European Urology*, 37, 161-171.
- 445 VAN KERREBROECK, P. E. V., VAN VOSKUILEN, A. C., HEESAKKERS, J. P. F. A., LYCKLAMA A NIJHOLT, A. A. B., SIEGEL, S., JONAS, U., FOWLER, C. J., FALL, M., GAJEWSKI, J. B., HASSOUNA, M. M., CAPPELLANO, F., ELHILALI, M. M., MILAM, D. F., DAS, A. K., DIJKEMA, H. E. & VAN DEN HOMBERGH, U. (2007) Results of sacral neuromodulation therapy for urinary voiding dysfunction: outcomes of a prospective, worldwide clinical study.[see comment]. *Journal of Urology*, 178, 2029-34.
- 446 VAN VOSKUILEN, A. C., OERLEMANS, D. J. A. J., WEIL, E. H. J., DE BIE, R. A. & VAN KERREBROECK, P. E. V. A. (2006) Long term results of neuromodulation by sacral nerve stimulation for lower urinary tract symptoms: a retrospective single center study. *European Urology*, 49, 366-72.
- 447 Brazzelli, M., Murray, A., Fraser, C.: Efficacy and safety of sacral nerve stimulation for urinary urge incontinence: a systematic review. *J Urol*, 175: 835, 2006
- 448 DANESHGARI, F., ZIMMERN, P. E. & JACOMIDES, L. (1999) Magnetic resonance imaging detection of symptomatic noncommunicating intraurethral wall diverticula in women. *J Urol*, 161, 1259-61; discussion 1261-2.
- 449 LEACH, G. E., SIRLS, L. T., GANABATHI, K. & ZIMMERN, P. E. (1993) L N S C3: a proposed classification system for female urethral diverticula. *NeuroUrol Urodyn*, 12, 523-31.
- 450 LENG, W. W., FAERBER, G., DEL TERZO, M. & MCGUIRE, E. J. (1999) Long-term outcome of incontinent ileovesicostomy management of severe lower urinary tract dysfunction. *Journal of Urology*, 161, 1803-1806
- 451 GANABATHI, K., LEACH, G. E., ZIMMERN, P. E. & DMOCHOWSKI, R. (1994) Experience with the management of urethral diverticulum in 63 women. *J Urol*, 152, 1445-52.
- 452 JACOBY, K. & ROWBOTHAM, R. K. (1999) Double balloon positive pressure urethrography is a more sensitive test than voiding cystourethrography for diagnosing urethral diverticulum in women. *J Urol*, 162, 2066-9.
- 453 GOLOMB, J., LEIBOVITCH, I., MOR, Y., MORAG, B. & RAMON, J. (2003) Comparison of voiding cystourethrography and double-balloon urethrography in the diagnosis of complex female urethral diverticula. *Eur Radiol*, 13, 536-42.
- 454 RUFFORD, J. & CARDOZO, L. (2004) Urethral diverticula: a diagnostic dilemma. *BJU Int*, 94, 1044-7.
- 455 LEE, T. G. & KELLER, F. S. (1977) Urethral diverticulum: diagnosis by ultrasound. *AJR Am J Roentgenol*, 128, 690-1.
- 456 YANG, S. X., YAO, Y., HU, Y. F., SONG, C., WANG, L. L. & JIN, H. M. (2004) Reconstruction of rabbit urethra using urethral extracellular matrix. *Chin Med J (Engl)*, 117, 1786-90.
- 457 GERRARD, E. R., JR., LLOYD, L. K., KUBRICHT, W. S. & KOLETTIS, P. N. (2003) Transvaginal ultrasound for the diagnosis of urethral diverticulum. *J Urol*, 169, 1395-7.
- 458 NEITLICH, J. D., FOSTER, H. E., JR., GLICKMAN, M. G. & SMITH, R. C. (1998) Detection of urethral diverticula in women: comparison of a high resolution fast spin echo technique with double balloon urethrography. *J Urol*, 159, 408-10
- 459 HAN, D. H., JEONG, Y. S., CHOO, M. S. & LEE, K. S. (2007) Outcomes of surgery of female urethral diverticula classified using magnetic resonance imaging. *Eur Urol*, 51, 1664-70.
- 460 LORENZO, A. J., ZIMMERN, P., LEMACK, G. E. & NURENBERG, P. (2003) Endorectal coil magnetic resonance imaging for diagnosis of urethral and periurethral pathologic findings in women. *Urology*, 61, 1129-33; discussion 1133-4.
- 461 LEACH, G. E. & BAVENDAM, T. G. (1987) Female urethral diverticula. *Urology*, 30, 407-15
- 462 SWIERZEWSKI, S. J., 3RD & MCGUIRE, E. J. (1993) Pubovaginal sling for treatment of female stress urinary incontinence complicated by urethral diverticulum. *J Urol*, 149, 1012-4.
- 463 KOCHAKARN, W., RATANA-OLARN, K., VISESHSINDH, V., LEENANUPUNTH, C. & MUANGMAN, V. (2000) Urethral diverticulum in females: 25 years experience at Ramathibodi Hospital. *J Med Assoc Thai*, 83, 1437-41.
- 464 TAIT, J., PEDDIE, B. A., BAILEY, R. R., ARNOLD, E. P., RUSSELL, G. L., BISHOP, V. A. & BURRY, A. F. (1985) Urethral syndrome (abacterial cystitis)--search for a pathogen. *Br J Urol*, 57, 552-6.
- 465 DAVIS, B. L. & ROBINSON, D. G. (1970) Diverticula of the female urethra: assay of 120 cases. *J Urol*, 104, 850-3.
- 466 LAPIDES, J. (1979) Transurethral treatment of urethral diverticula in women. *J Urol*, 121, 736-8.
- 467 ELLIK, M. (1957) Diverticulum of the female urethra: a new method of ablation. *J Urol*, 77, 243-6.
- 468 SPENCE, H. M. & DUCKETT, J. W., JR. (1970) Diverticulum of the female urethra: clinical aspects and presentation of a simple operative technique for cure. *J Urol*, 104, 432-7.
- 469 ROVNER, E. S. & WEIN, A. J. (2003) Diagnosis and reconstruction of the dorsal or circumferential urethral diverticulum. *J Urol*, 170, 82-6; discussion 86.
- 470 LJUNGQVIST, L., PEEKER, R. & FALL, M. (2007) Female urethral diverticulum: 26-year followup of a large series. *J Urol*, 177, 219-24; discussion 224.
- 471 ARROWSMITH, S., HAMLIN, E. C. & WALL, L. L. (1996) Obstructed labor injury complex: obstetric fistula formation and the multifaceted morbidity of maternal birth trauma in the developing world. *Obstet Gynecol Surv*, 51, 568-74.
- 472 JONAS, D., HANKE, P. & WEBER, W. (1984) [Urologic traumatology in childhood (closed injuries)]. *Unfallchirurgie*, 10, 73-80.
- 473 SYMMONDS, R. E. (1984) Incontinence: vesical and urethral fistulas. *Clin Obstet Gynecol*, 27, 499-514.
- 474 LEE, Y. T. & LEE, J. M. (1988) Delayed retropubic urethroplasty of completely transected female membranous urethra. *Urology*, 31, 499-502.
- 475 TANCER, M. L. (1992) Observations on prevention and management of vesicovaginal fistula after total hysterectomy. *Surg Gynecol Obstet*, 175, 501-6.
- 476 KURSH, E. D., MORSE, R. M., RESNICK, M. I. & PERSKY, L. (1988) Prevention of the development of a vesicovaginal fistula. *Surg Gynecol Obstet*, 166, 409-12.
- 477 GOODWIN, W. E. & SCARDINO, P. T. (1980) Vesicovaginal and ureterovaginal fistulas: a summary of 25 years of experience. *J Urol*, 123, 370-4.
- 478 BLANDY, J. P., BADENOCH, D. F., FOWLER, C. G., JENKINS, B. J. & THOMAS, N. W. (1991) Early repair of iatrogenic injury to the ureter or bladder after gynecological surgery. *J Urol*, 146, 761-5.
- 479 HARRISS, D. R. (1995) Smooth muscle cell culture: a new



- approach to the study of human detrusor physiology and pathophysiology. *Br J Urol*, 75 Suppl 1, 18-26
- 480 GILMOUR, D. T., DWYER, P. L. & CAREY, M. P. (1999) Lower urinary tract injury during gynecologic surgery and its detection by intraoperative cystoscopy. *Obstet Gynecol*, 94, 883-9.
- 481 ARMENAKAS, N. A., PAREEK, G. & FRACCHIA, J. A. (2004) Iatrogenic bladder perforations: longterm followup of 65 patients. *J Am Coll Surg*, 198, 78-82.
- 482 EILBER, K. S., KAVALER, E., RODRIGUEZ, L. V., ROSENBLUM, N. & RAZ, S. (2003) Ten-year experience with transvaginal vesicovaginal fistula repair using tissue interposition. *J Urol*, 169, 1033-6.
- 483 KOTTMEIER, H. L. (1964) Complications Following Radiation Therapy in Carcinoma of the Cervix and Their Treatment. *Am J Obstet Gynecol*, 88, 854-66.
- 484 CUSHING, R. M., TOVELL, H. M. & LIEGNER, L. M. (1968) Major urologic complications following radium and x-ray therapy for carcinoma of the cervix. *Am J Obstet Gynecol*, 101, 750-5.
- 485 LEE, U. J., GOLDMAN, H., MOORE, C., DANESHGARI, F., RACKLEY, R. R. & VASAVADA, S. P. (2008) Rate of de novo stress urinary incontinence after urethral diverticulum repair. *Urology*, 71, 849-53.
- 486 VILLASANTA, U. (1972) Complications of radiotherapy for carcinoma of the uterine cervix. *Am J Obstet Gynecol*, 114, 717-26.
- 487 CROSS, S. B. & COPAS, P. R. (1993) Colovaginal fistula secondary to diverticular disease. A report of two cases. *J Reprod Med*, 38, 905-6.
- 488 BA-THIKE, K., THAN, A. & NAN, O. (1992) Tuberculous vesico-vaginal fistula. *Int J Gynaecol Obstet*, 37, 127-30.
- 489 GOLDSTEIN, I., WISE, G. J. & TANCER, M. L. (1990) A vesicovaginal fistula and intravesical foreign body. A rare case of the neglected pessary. *Am J Obstet Gynecol*, 163, 589-91.
- 490 COLOMBEL, M., PEDRON, P., MISSIRLU, A., ABBOU, C. & CHOPIN, D. (1995) Vesicovaginal fistula after laser vaporization of vaginal condyloma. *J Urol*, 154, 1860.
- 491 MONTEIRO, H., NOGUEIRA, R. & DE CARVALHO, H. (1995) Behcet's syndrome and vesicovaginal fistula: an unusual complication. *J Urol*, 153, 407-8.
- 492 DRUTZ, H. P. & MAINPRIZE, T. C. (1988) Unrecognized small vesicovaginal fistula as a cause of persistent urinary incontinence. *Am J Obstet Gynecol*, 158, 237-40.
- 493 GRAHAM, J. B. (1965) Vaginal Fistulas Following Radiotherapy. *Surg Gynecol Obstet*, 120, 1019-30.
- 494 BALL, T. (1998) Editorial comment on Ginsberg et al: Posthysterectomy vaginal vault fistula: diagnosis and management. *Urology*, 51: 61-65
- 495 GINSBERG, D. A., ROVNER, E. S. & RAZ, S. (1998) Posthysterectomy vaginal cuff fistula: diagnosis and management of an unusual cause of "incontinence". *Urology*, 52, 61-4; discussion 64-5.
- 496 ZIMMERN, P. E., HADLEY, H. R., LEACH, G. E. & RAZ, S. (1987) Female urethral obstruction after Marshall-Marchetti-Krantz operation. *J Urol*, 138, 517-20.
- 497 HILTON, P. (1998) Urodynamic findings in patients with urogenital fistulae. *Br J Urol*, 81, 539-42.
- 498 O'CONNOR, V. J., JR. (1980) Review of experience with vesicovaginal fistula repair. *J Urol*, 123, 367-9.
- 499 ALONSO, J. J., JIMENEZ CRUZ, J. F., MILLAN, M. C., MAYORDOMO, F. & VALLS, F. (1985) [Ultrastructural study of urinary lithiasis. Oxalo-calcic lithiasis. I: Helicoid fibers]. *Arch Esp Urol*, 38, 439-43.
- 500 MOLINA, L. R., LYNNE, C. M. & POLITANO, V. A. (1989) Treatment of vesicouterine fistula by fulguration. *J Urol*, 141, 1422-3.
- 501 STOVSKY, M. D., IGNATOFF, J. M., BLUM, M. D., NANNINGA, J. B., O'CONNOR, V. J. & KURSH, E. D. (1994) Use of electrocoagulation in the treatment of vesicovaginal fistulas. *J Urol*, 152, 1443-4
- 502 MCKAY, H. A. (1997) Vesicovaginal and vesicocutaneous fistulas: transurethral suture cystorrhaphy as a new closure technique. *J Urol*, 158, 1513-6.
- 503 EVANS, L. A., FERGUSON, K. H., FOLEY, J. P., ROZANSKI, T. A. & MOREY, A. F. (2003) Fibrin sealant for the management of genitourinary injuries, fistulas and surgical complications. *J Urol*, 169, 1360-2.
- 504 O'CONNOR, V. J., JR. (1971) Management of urinary tract injuries following surgery. *J Okla State Med Assoc*, 64, 150-4.
- 505 WEIN, A. J., MALLOY, T. R., CARPINIELLO, V. L., GREENBERG, S. H. & MURPHY, J. J. (1980) Repair of vesicovaginal fistula by a suprapubic transvesical approach. *Surg Gynecol Obstet*, 150, 57-60.
- 506 PERSKY, L., HERMAN, G. & GUERRIER, K. (1979) Nondelay in vesicovaginal fistula repair. *Urology*, 13, 273-5.
- 507 WANG, Y. & HADLEY, H. R. (1990) Nondelayed transvaginal repair of high lying vesicovaginal fistula. *J Urol*, 144, 34-6
- 508 BLAIVAS, J. G., HERITZ, D. M. & ROMANZI, L. J. (1995) Early versus late repair of vesicovaginal fistulas: vaginal and abdominal approaches. *J Urol*, 153, 1110-2; discussion 1112-3.
- 509 WANG, Y. & HADLEY, H. R. (1990) Nondelayed transvaginal repair of high lying vesicovaginal fistula. *J Urol*, 144, 34-6.
- 510 TOMLINSON, A. J. & THORNTON, J. G. (1998) A randomised controlled trial of antibiotic prophylaxis for vesico-vaginal fistula repair. *British Journal of Obstetrics & Gynaecology*, 105, 397-9.
- 511 DUPONT, M. C., ALBO, M. E. & RAZ, S. (1996) Diagnosis of stress urinary incontinence. An overview. *Urol Clin North Am*, 23, 407-15.
- 512 ZEIDMAN, E. J., CHIANG, H., ALARCON, A. & RAZ, S. (1988) Suprapubic cystostomy using Lowsley retractor. *Urology*, 32, 54-5.
- 513 RAZ, S., NITTI, V. W. & BREGG, K. J. (1993) Transvaginal repair of enterocele. *J Urol*, 149, 724-30.
- 514 BLAIVAS, J. G. & GROUTZ, A. (2000) Bladder outlet obstruction nomogram for women with lower urinary tract symptomatology. *Neurourol Urodyn*, 19, 553-64.
- 515 HOSKINS, W. J., PARK, R. C., LONG, R., ARTMAN, L. E. & MCMAHON, E. B. (1984) Repair of urinary tract fistulas with bulboocavernosus myocutaneous flaps. *Obstet Gynecol*, 63, 588-93.
- 517 GHONIEM, G. M. & MONGA, M. (1995) Modified pubovaginal sling and Martius graft for repair of the recurrent vesicovaginal fistula involving the internal urinary sphincter. *Eur Urol*, 27, 241-5.
- 518 RANGNEKAR, N. P., IMDAD ALI, N., KAUL, S. A. & PATHAK, H. R. (2000) Role of the martius procedure in the management of urinary-vaginal fistulas. *J Am Coll Surg*, 191, 259-63.
- 519 ENZELSBERGER, H. & GITSCH, E. (1991) Surgical management of vesicovaginal fistulas according to Chassar Moir's method. *Surg Gynecol Obstet*, 173, 183-6.
- 520 ISELIN, C. E., ASLAN, P. & WEBSTER, G. D. (1998) Transvaginal repair of vesicovaginal fistulas after hysterectomy by vaginal cuff excision. *J Urol*, 160, 728-30.
- 521 FLYNN, M. K., PETERSON, A. C., AMUNDSEN, C. L. & WEBSTER, G. D. (2004) Functional outcomes of primary and secondary repairs of vesicovaginal fistulae via vaginal cuff scar excision. *Int Urogynecol J Pelvic Floor Dysfunct*, 15, 394-8; discussion 398
- 522 GIL-VERNET, J. M., GIL-VERNET, A. & CAMPOS, J. A. (1989) New surgical approach for treatment of complex vesicovaginal fistula. *J Urol*, 141, 513-6.
- 523 NESRALLAH, L. J., SROUGI, M. & GITTES, R. F. (1999) The O'Conor technique: the gold standard for supratrigonal vesicovaginal fistula repair. *J Urol*, 161, 566-8.
- 524 WEIN, A. J., MALLOY, T. R., CARPINIELLO, V. L., GREENBERG, S. H. & MURPHY, J. J. (1980) Repair of vesicovaginal fistula by a suprapubic transvesical approach. *Surg Gynecol Obstet*, 150, 57-60.
- 525 TURNER-WARWICK, R. (1976) Complex traumatic posterior



- urethral strictures. *Trans Am Assoc Genitourin Surg*, 68, 60-72.
- 526 KIRICUTA, I. & GOLDSTEIN, A. M. (1972) The repair of extensive vesicovaginal fistulas with pedicled omentum: a review of 27 cases. *J Urol*, 108, 724-7.
- 527 MARSHALL, V. F. (1979) Vesicovaginal fistulas on one urological service. *J Urol*, 121, 25-9.
- 528 UDEH, F. N. (1985) Simple management of difficult vesicovaginal fistulas by anterior transvesical approach. *J Urol*, 133, 591-3.
- 529 DEMIREL, A., POLAT, O., BAYRAKTAR, Y., GUL, O. & OKYAR, G. (1993) Transvesical and transvaginal reparation in urinary vaginal fistulas. *Int Urol Nephrol*, 25, 439-44.
- 530 KRISTENSEN, J. K. & LOSE, G. (1994) Vesicovaginal fistulas: the transperitoneal repair revisited. *Scand J Urol Nephrol Suppl*, 157, 101-5.
- 531 NEZHAT, C. H., NEZHAT, F., NEZHAT, C. & ROTTENBERG, H. (1994) Laparoscopic repair of a vesicovaginal fistula: a case report. *Obstet Gynecol*, 83, 899-901.
- 532 GARLOCK, J. H. (1928) The Treatment of Compound Injuries of the Extremities. *Ann Surg*, 87, 321-54.
- 533 BYRON, R. L., JR. & OSTERGARD, D. R. (1969) Sartorius muscle interposition for the treatment of the radiation-induced vaginal fistula. *Am J Obstet Gynecol*, 104, 104-7.
- 534 STIRNEMANN, H. (1969) Treatment of recurrent rectovaginal fistula by interposition of a glutaeus maximus muscle flap. *Am J Proctol*, 20, 52-4.
- 535 MENCHACA, A., AKHYAT, M., GLEICHER, N., GOTTLIEB, L. & BERNSTEIN, J. (1990) The rectus abdominis muscle flap in a combined abdominovaginal repair of difficult vesicovaginal fistulae. A report of three cases. *J Reprod Med*, 35, 565-8.
- 536 BLAIVAS, J. G. (1991) Treatment of female incontinence secondary to urethral damage or loss. *Urol Clin North Am*, 18, 355-63.
- 537 CANDIANI, P., AUSTONI, E., CAMPIGLIO, G. L., CERESOLI, A., ZANETTI, G. & COLOMBO, F. (1993) Repair of a recurrent urethrovaginal fistula with an island bulbocavernous musculocutaneous flap. *Plast Reconstr Surg*, 92, 1393-6.
- 538 TANCER, M. L. (1993) A report of thirty-four instances of urethrovaginal and bladder neck fistulas. *Surg Gynecol Obstet*, 177, 77-80.
- 539 BRANDT, F. T., LORENZATO, F. R. & ALBUQUERQUE, C. D. (1998) Treatment of vesicovaginal fistula by bladder mucosa autograf technique. *J Am Coll Surg*, 186, 645-8.
- 540 PATIL, U., WATERHOUSE, K. & LAUNGANI, G. (1980) Management of 18 difficult vesicovaginal and urethrovaginal fistulas with modified Ingelman-Sundberg and Martius operations. *J Urol*, 123, 653-6.
- 541 BISSADA, S. A. & BISSADA, N. K. (1992) Repair of active radiation-induced vesicovaginal fistula using combined gastric and omental segments based on the gastroepiploic vessels. *J Urol*, 147, 1368-70.
- 542 OBRINK, A. & BUNNE, G. (1978) Gracilis interposition in fistulas following radiotherapy for cervical cancer. A retrospective study. *Urol Int*, 33, 370-6.
- 543 OU, C. S., HUANG, U. C., TSUANG, M. & ROWBOTHAM, R. (2004) Laparoscopic repair of vesicovaginal fistula. *J Laparoendosc Adv Surg Tech A*, 14, 17-21.
- 544 ELKINS, T. E. (1994) Surgery for the obstetric vesicovaginal fistula: a review of 100 operations in 82 patients. *Am J Obstet Gynecol*, 170, 1108-18; discussion 1118-20.
- 545 WEBSTER, G. D., SIHELNIK, S. A. & STONE, A. R. (1984) Urethrovaginal fistula: a review of the surgical management. *J Urol*, 132, 460-2.
- 546 BLAIVAS, J. G. & HERITZ, D. M. (1996) Vaginal flap reconstruction of the urethra and vesical neck in women: a report of 49 cases. *J Urol*, 155, 1014-7.
- 547 HENDREN, W. H. (1980) Reconstructive problems of the vagina and the female urethra. *Clin Plast Surg*, 7, 207-34.
- 548 HENDREN, W. H. (1998) Construction of a female urethra using the vaginal wall and a buttock flap: experience with 40 cases. *J Pediatr Surg*, 33, 180-7.
- 549 BLAIVAS, J. G. (1990) Diagnostic evaluation of incontinence in patients with neurologic disease. *J Am Geriatr Soc*, 38, 306-10.
- 550 LEACH, G. E. (1991) Urethrovaginal fistula repair with Martius labial fat pad graft. *Urol Clin North Am*, 18, 409-13.
- 551 GRIFFITHS, C. D. (1982) Pyeloduodenal fistula. *J R Coll Surg Edinb*, 27, 241-2.
- 552 CARDOZO, L. D. & STANTON, S. L. (1980) Genuine stress incontinence and detrusor instability--a review of 200 patients. *Br J Obstet Gynaecol*, 87, 184-90.
- 553 JENSEN, L. M., AABECH, J., LUNDEVALL, F. & IVERSEN, H. G. (1996) Female urethral diverticulum. Clinical aspects and a presentation of 15 cases. *Acta Obstet Gynecol Scand*, 75, 748-52.
- 554 VAN WAALWIJK VAN DOORN, E. S., REMMERS, A. & JANKNEGHT, R. A. (1991) Extramural ambulatory urodynamic monitoring during natural filling and normal daily activities: evaluation of 100 patients. *J Urol*, 146, 124-31.
- 555 BLAIVAS, J. G. (1989) Vaginal flap urethral reconstruction: an alternative to the bladder flap neourethra. *J Urol*, 141, 542-5.
- 557 WEBB, R. J., RAMSDEN, P. D. & NEAL, D. E. (1991) Ambulatory monitoring and electronic measurement of urinary leakage in the diagnosis of detrusor instability and incontinence. *Br J Urol*, 68, 148-52.
- 558 YALCIN, O., ISIKOGLU, M. & BEJI, N. K. (2004) Results of TVT operations alone and combined with other vaginal surgical procedures. *Arch Gynecol Obstet*, 269, 96-8.
- 559 SIMONS, A. M., YOONG, W. C., BUCKLAND, S. & MOORE, K. H. (2001) Inadequate repeatability of the one-hour pad test: the need for a new incontinence outcome measure. *BJOG*, 108, 315-9.
- 560 KARANTANIS, E., ALLEN, W., STEVERMUEER, T. L., SIMONS, A. M., O'SULLIVAN, R. & MOORE, K. H. (2005) The repeatability of the 24-hour pad test. *Int Urogynecol J Pelvic Floor Dysfunct*, 16, 63-8; discussion 68
- 561 DYLEWSKI, D. A., JAMISON, M. G., BORAWSKI, K. M., SHERMAN, N. D., AMUNDSEN, C. L. & WEBSTER, G. D. (2007) A statistical comparison of pad numbers versus pad weights in the quantification of urinary incontinence. *Neurourol Urodyn*, 26, 3-7.
- 562 WYMAN, J. F., CHOI, S. C., HARKINS, S. W., WILSON, M. S. & FANTL, J. A. (1988) The urinary diary in evaluation of incontinent women: a test-retest analysis. *Obstet Gynecol*, 71, 812-7.
- 563 WYRWICH, K. W., BULLINGER, M., AARONSON, N., HAYS, R. D., PATRICK, D. L. & SYMONDS, T. (2005) Estimating clinically significant differences in quality of life outcomes. *Qual Life Res*, 14, 285-95.
- 564 KELLEHER, C. J., PLEIL, A. M., REESE, P. R., BURGESS, S. M. & BRODISH, P. H. (2004) How much is enough and who says so? *BJOG*, 111, 605-12.
- 565 YALCIN, I., PATRICK, D. L., SUMMERS, K., KINCHEN, K. & BUMP, R. C. (2006) Minimal clinically important differences in Incontinence Quality-of-Life scores in stress urinary incontinence. *Urology*, 67, 1304-8.
- 566 HENDRIKS, M. R., EVERS, S. M., BLEIJLEVEN, M. H., VAN HAASSTREGT, J. C., CREBOLDER, H. F. & VAN EIJK, J. T. (2008) Cost-effectiveness of a multidisciplinary fall prevention program in community-dwelling elderly people: a randomized controlled trial (ISRCTN 64716113). *Int J Technol Assess Health Care*, 24, 193-202.
- 567 NORTON, C. (1982) The effects of urinary incontinence in women. *Int Rehabil Med*, 4, 9-14.
- 568 WEBER, A. M., ABRAMS, P., BRUBAKER, L., CUNDIFF, G., DAVIS, G., DMOCHOWSKI, R. R., FISCHER, J., HULL, T., NYGAARD, I. & WEIDNER, A. C. (2001) The standardization of terminology for researchers in female pelvic floor disorders. *Int Urogynecol J Pelvic Floor Dysfunct*, 12, 178-86.
- 569 BRAZIER, J. (2008) Measuring and valuing mental health for use in economic evaluation. *J Health Serv Res Policy*, 13 Suppl 3, 70-5.
- 570 GHONIEM, G., STANFORD, E., KENTON, K., ACHTARI, C., GOLDBERG, R., MASCARENHAS, T., PAREKH, M., TAMUSSINO, K., TOSSON, S., LOSE, G. & PETRI, E. (2008) Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological Association (IUGA) guidelines for research and clinical practice. *Int Urogynecol J Pelvic Floor Dysfunct*, 19, 5-33

- 571 MATTIASSON, A., DJURHUUS, J. C., FONDA, D., LOSE, G., NORDLING, J. & STOHRER, M. (1998) Standardization of outcome studies in patients with lower urinary tract dysfunction: a report on general principles from the Standardisation Committee of the International Continence Society. *Neurourol Urodyn*, 17, 249-53.
- 572 WANG, Y. & HADLEY, H. R. (1991) Management of persistent or recurrent urinary incontinence after placement of artificial urinary sphincter. *J Urol*, 146, 1005-6.
- 573 COSTA, P., et al: The use of an artificial urinary sphincter in women with type III incontinence and a negative Marshall test. *J Urol* 165(4): 1172, 2001
- 574 HEITZ, M., OLIANAS, R., SCHREITER, F.: [Therapy of female urinary incontinence with the AMS 800 artificial sphincter. Indications, outcome, complications and risk factors]. *Urologe A*, 36: 426, 1997
- 575 APPELL, R.: Techniques and results in the implantation of the artificial urinary sphincter in women with type III stress urinary incontinence by a vaginal approach. *neurourol urodyn*, 7: 613, 1988
- 576 WEBSTER, G. D., PEREZ, L. M., KHOURY, J. M. et al.: Management of type III stress urinary incontinence using artificial urinary sphincter. *Urology*, 39: 499, 1992
- 577 SANZ MYAYO E, G. G. I., FRENANDEZ FERNANDEZ E, PERALES CABANAS L, et al: AMS-800 artificial sphincter. Our experience in the last 20 years. *Arch Esp Urol.*, 56(9): 989, 2003
- 578 NGNINKEU, B. N., VAN HEUGEN, G., DI GREGORIO, M. et al.: Laparoscopic artificial urinary sphincter in women for type III incontinence: preliminary results. *Eur Urol*, 47: 793, 2005
- 579 SHAIKH, S., ONG, E. K., GLAVIND, K. et al.: Mechanical devices for urinary incontinence in women. *Cochrane Database Syst Rev*, 3: CD001756, 2006
- 580 GRIFFITHS, C. J., ASSI, M. S., STYLES, R. A., RAMSDEN, P. D. & NEAL, D. E. (1989) Ambulatory monitoring of bladder and detrusor pressure during natural filling. *J Urol*, 142, 780-4.
- 581 ZACCHARIN, R. (1968) The anatomic support of the female urethra. *Obstet Gynecol*, 21, 754-759.
- 582 DELANCEY, J. O. (1994) Structural support of the urethra as it relates to stress urinary incontinence: the hammock hypothesis. *Am J Obstet Gynecol*, 170, 1713-20; discussion 1720-3.
- 583 HUISMAN, A. B. (1983) Aspects on the anatomy of the female urethra with special relation to urinary continence. *Contrib Gynecol Obstet*, 10, 1-31.
- 584 WESTBY M, A. M., ULMSTEN U. (1982) Location of maximum intraurethral pressure related to urogenital diaphragm in the female subject as studied by simultaneous urethrocytometry and voiding urethrocytography. *Am J Obstet Gynecol*, 144, 408-412.
- 585 ASMUSSEN, M. & ULMSTEN, U. (1983) On the physiology of continence and pathophysiology of stress incontinence in the female. *Contrib Gynecol Obstet*, 10, 32-50.
- 586 NOVARA, G., FICARRA, V., BOSCOLO-BERTO, R., SECCO, S., CAVALLERI, S. & ARTIBANI, W. (2007) Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness. *Eur Urol*, 52, 663-78.
- 587 BALAKRISHNAN, S., LIM, Y. N., BARRY, C., CORSTIAANS, A., KANNAN, K., RANE, A., BALAKRISHNAN, S., LIM, Y. N., BARRY, C., CORSTIAANS, A., KANNAN, K. & RANE, A. (2007) Sling distress: a subanalysis of the IVS tapes from the SUSPEND trial. *Australian & New Zealand Journal of Obstetrics & Gynaecology*, 47, 496-8.
- 588 DELORME, E. (2001) [Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women]. *Prog Urol*, 11, 1306-13.
- 589 DE LEVAL, J. (2003) Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. *Eur Urol*, 44, 724-30.
- 590 WANG, A. C., LIN, Y. H., TSENG, L. H., CHIH, S. Y. & LEE, C. J. (2006) Prospective randomized comparison of transobturator suburethral sling (Monarc) vs suprapubic arc (Sparc) sling procedures for female urodynamic stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*, 17, 439-43.
- 591 BUT I, F. M. (2008) Complications and short-term results of two difference transobturator techniques for surgical treatment of women with urinary incontinence: a randomized study. *Int Urogynecol J Pelvic Floor Dysfunct*; published online.
- 592 LEE K-Y, C. M.-S., LEE YS, HAN J-Y, KIM J-Y, JUNG BJ, HAN DH (2008) Prospective comparison of the inside-out and outside-in transobturator-tape procedures for treatment of femal stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*, 19, 577-582.
- 593 LATTHE, P. M., FOON, R. & TOOZS-HOBSON, P. (2007) Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. *BJOG*, 114, 522-31.
- 594 DOOLEY, Y., KENTON, K., CAO, G., LUKE, A., DURAZO-ARVIZU, R., KRAMER, H. & BRUBAKER, L. (2008) Urinary incontinence prevalence: results from the National Health and Nutrition Examination Survey. *J Urol*, 179, 656-61.
- 595 RAGINS, A. I., SHAN, J., THOM, D. H., SUBAK, L. L., BROWN, J. S. & VAN DEN EEDEN, S. K. (2008) Effects of urinary incontinence, comorbidity and race on quality of life outcomes in women. *J Urol*, 179, 651-5; discussion 655.
- 596 VARNER, R. E. (1990) Retropubic long-needle suspension procedures for stress urinary incontinence. *Am J Obstet Gynecol*, 163, 551-7.
- 597 ZIVKOVIC, F., TAMUSSINO, K., PIEBER, D. & HAAS, J. (1999) Body mass index and outcome of incontinence surgery. *Obstetrics & Gynecology*, 93, 753-756.
- 598 HELLBERG, D., HOLMGREN, C., LANNER, L. & NILSSON, S. (2007) The very obese woman and the very old woman: tension-free vaginal tape for the treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*, 18, 423-9.
- 599 KUO, H. C. (2007) Effect of detrusor function on the therapeutic outcome of a suburethral sling procedure using a polypropylene sling for stress urinary incontinence in women. *Scand J Urol Nephrol*, 41, 138-43.
- 600 GORDON, D., GOLD, R. S., PAUZNER, D., LESSING, J. B. & GROUTZ, A. (2001) Combined genitourinary prolapse repair and prophylactic tension-free vaginal tape in women with severe prolapse and occult stress urinary incontinence: preliminary results. *Urology*, 58, 547-50.
- 601 ANGER, J. T., RODRIGUEZ, L. V., WANG, Q., PASHOS, C. L. & LITWIN, M. S. (2007) The role of provider volume on outcomes after sling surgery for stress urinary incontinence. *J Urol*, 177, 1457-62; discussion 1462.
- 602 ZIMMERN, P. E. & MIYAZAKI, F. (1994) Pudendal enterocele with bladder involvement. *Urology*, 44, 918-21.
- 603 ZULLO, F., MORELLI, M., RUSSO, T., IUZZOLINO, D. & PALOMBA, S. (2002) Two techniques of laparoscopic retropubic urethropexy. *Journal of the American Association of Gynecologic Laparoscopists*, 9, 178-181.
- 604 ZULLO, F., PALOMBA, S., RUSSO, T., SBANO, F. M., FALBO, A., MORELLI, M., PELLICANO, M. & MASTRANTONIO, P. (2004) Laparoscopic colposuspension using sutures or prolene meshes: a 3-year follow-up. *European Journal of Obstetrics, Gynecology, & Reproductive Biology*, 117, 201-203.
- 605 VALPAS, A., KIVELA, A., PENTTINEN, J., KAUKO, M., KUJANSUU, E., TOMAS, E., HAARALA, M., MELTOMAA, S., NILSSON, C. K., (2003) Tension-free vaginal tape and laparoscopic mesh colposuspension in the treatment of stress urinary incontinence: immediate outcome and complications--a randomized clinical trial. *Acta Obstetrica et Gynecologica Scandinavica*, 82, 665-71.
- 606 HOMMA, Y., Y. KONDO, et al. (2000). Reproducibility of cystometry in overactive detrusor. *Eur Urol* 38(6): 681-5.
- 607 REZAPOUR M and ULMSTEN U. (2001) Tension-Free Vaginal Tape (TVT) in women with mixed urinary incontinence - A long-term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 12 (Suppl 2) 15-18